de: 4120-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 431, 438, 441, 447

[CMS-2442-P]

RIN 0938-AU68

Medicaid Program; Ensuring Access to Medicaid Services

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and

Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule takes a comprehensive approach to improving access to care,

quality and health outcomes, and better addressing health equity issues in the Medicaid program

across fee-for-service (FFS), managed care delivery systems, and in home and community-based

services (HCBS) programs. These proposed improvements seek to increase transparency and

accountability, standardize data and monitoring, and create opportunities for States to promote

active beneficiary engagement in their Medicaid programs, with the goal of improving access to

care.

DATES: To be assured consideration, comments must be received at one of the addresses

provided below, by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER].

ADDRESSES: In commenting, please refer to file code CMS-2442-P.

Comments, including mass comment submissions, must be submitted in one of the

following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to

http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2442-P,

P.O. Box 8016,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-2442-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Karen LLanos, (410) 786-9071, for Medical Care Advisory Committee.

Jennifer Bowdoin, (410) 786-8551, for Home and Community-Based Services.

Jeremy Silanskis, (410) 786-1592, for Fee-for-Service Payment.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been

received: http://www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Overview

Title XIX of the Social Security Act (the Act) established the Medicaid program as a joint Federal and State program to provide medical assistance to eligible individuals, including many with low incomes. Under the Medicaid program, each State that chooses to participate in the program and receive Federal financial participation (FFP) for program expenditures, establishes eligibility standards, benefits packages, and payment rates, and undertakes program administration in accordance with Federal statutory and regulatory requirements. The provisions of each State's Medicaid program are described in the Medicaid "State plan" and, as applicable, related authorities, such as demonstration projects and waivers of State plan requirements. Among other responsibilities, CMS approves State plans, State plan amendments (SPAs), demonstration projects authorized under section 1115 of the Act, and waivers authorized under section 1915 of the Act; and reviews expenditures for compliance with Federal Medicaid law, including the requirements of section 1902(a)(30)(A) of the Act relating to efficiency, economy, quality of care, and access to ensure that all applicable Federal requirements are met.

As of December 2022, the Medicaid program provides essential health care coverage to more than 85 million¹ individuals, and, in 2021, accounted for 17 percent of national health expenditures.² The program covers a broad array of health benefits and services critical to

¹ December 2022 Medicaid and CHIP Enrollment Snapshot. Accessed at https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.

² CMS National Health Expenditure Accounts. National Health Expenditures 2020 Highlight. Accessed at https://www.cms.gov/files/document/highlights.pdf.

underserved populations,³ including low-income adults, children, parents, pregnant individuals, older adults, and people with disabilities. For example, Medicaid pays for approximately 41 percent of all births in the US⁴ and is the largest payer of long-term services and supports (LTSS),⁵ the largest, single payer of services to treat substance use disorders,⁶ and services to prevent and treat the Human Immunodeficiency Virus.⁷

On January 28, 2021, the President signed Executive Order (EO) 14009,8 "Strengthening Medicaid and the Affordable Care Act" which established the policy objective to protect and strengthen Medicaid and the Affordable Care Act and to make high-quality health care accessible and affordable for every American and directed executive departments and agencies to review existing regulations, orders, guidance documents, and policies to determine whether such agency actions are inconsistent with this policy. On April 5, 2022, EO 14070,9 "Continuing To Strengthen Americans' Access to Affordable, Quality Health Coverage," directed Federal agencies with responsibilities related to Americans' access to health coverage to review agency actions to identify ways to continue to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. This proposed rule aims to fulfill EOs 14009 and 14070 by helping States to strengthen Medicaid and improve access to and quality of care provided.

Ensuring that beneficiaries can access covered services is necessary to the basic operation of the Medicaid program. Depending on the State and its Medicaid program structure,

³ Executive Order 13985: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

⁴ National Center for Health Statistics. Key Birth Statistics. Accessed at https://www.cdc.gov/nchs/nvss/births.htm.

⁵ Colello, Kirsten J. Who Pays for Long-Term Services and Supports? Congressional Research Service. Updated June 15, 2022. Accessed at https://crsreports.congress.gov/product/pdf/IF/IF10343.

⁶ Soni, Anita. Health Care Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019. Statistical Brief #539, pg 12. February 2022. Agency for Healthcare Research and Quality, Rockville, MD. Accessed at https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf.

⁷ Dawson, L. and Kates, J. Insurance Coverage and Viral Suppression Among People with HIV, 2018. September 2020. Kaiser Family Foundation. Accessed at https://www.kff.org/hivaids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/.

⁸ Executive Order 14009: https://www.federalregister.gov/documents/2021/02/02/2021-02252/strengthening-medicaid-and-the-affordable-care-act.

⁹ Executive Order 14070: https://www.federalregister.gov/documents/2022/04/08/2022-07716/continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage.

beneficiaries access their health care services using a variety of care delivery systems (for example, FFS, fully-capitated managed care, partially capitated managed care, etc.), including through demonstrations and waiver programs. In 2020, 70 percent of Medicaid beneficiaries were enrolled in comprehensive managed care plans; ¹⁰ the remaining individuals received all of their care or some services that have been carved out of managed care through FFS.

Current access regulations are neither comprehensive nor consistent across delivery systems or coverage authority (for example, State plan and demonstration authority). For example, regulations at 42 CFR 447.203 and 447.204 relating to access to care, service payment rates, and Medicaid provider participation in rate setting apply only to Medicaid FFS delivery systems and focus on ensuring that payment rates are consistent with the statutory requirements in section 1902(a)(30)(A) of the Act. The regulations do not apply to services delivered under managed care. These regulations are also largely procedural in nature and rely heavily on States to form an analysis and reach conclusions on the sufficiency of their own payment rates.

With a program as large and complex as Medicaid, access regulations need to be multi-factorial to promote consistent access to health care for all beneficiaries across all types of care delivery systems in accordance with statutory requirements. Strategies to enhance access to health care services should reflect how people move through and interact with the health care system. We view the continuum of health care access across three dimensions of a person-centered framework: (1) enrollment in coverage; (2) maintenance of coverage; and (3) access to services and supports. Within each of these dimensions, accompanying regulatory, monitoring, and/or compliance actions may be needed to ensure access to health care is achieved and maintained.

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¹⁰MACPAC 2022 Analysis of T-MSIS data February 2022. Exhibit 30. Percentage of Medicaid Enrollees in Managed Care by State and Eligibility Group https://www.macpac.gov/wp-content/uploads/2022/12/EXHIBIT-30.-Percentage-of-Medicaid-Enrollees-in-Managed-Care-by-State-and-Eligibility-Group-FY-2020.pdf.

In the spring of 2022, we released a request for information (RFI)¹¹ to collect feedback on a broad range of questions that examined topics such as: challenges with eligibility and enrollment; ways we can use data available to measure, monitor, and support improvement efforts related to access to services; strategies we can implement to support equitable and timely access to providers and services; and opportunities to use existing and new access standards to help ensure that Medicaid and CHIP payments are sufficient to enlist enough providers.

Some of the most common feedback we received through the RFI related to ways that we can promote health equity through cultural competency. Commenters shared the importance that cultural competency plays in how beneficiaries access health care and in the quality of health services received by beneficiaries. The RFI respondents shared examples of actions that we could take, including collecting and analyzing health outcomes data by sociodemographic categories; establishing minimum standards for how States serve communities in ways that address cultural competency and language preferences; and reducing barriers to enrollment and retention for racial and ethnic minority groups.

In addition to the topic of cultural competency, commenters also commonly shared that they viewed reimbursement rates as a key driver of provider participation in Medicaid and CHIP programs. Further, commenters noted that aligning payment approaches and setting minimum standards for payment regulations and compliance across Medicaid and CHIP delivery systems, services, and benefits could help ensure that beneficiaries' access to services is as similar as possible across beneficiary groups, delivery systems, and programs.

As mentioned previously in this proposed rule, the first dimension of access focuses on ensuring that eligible people are able to enroll in the Medicaid program. Access to Medicaid enrollment requires that a potential beneficiary know if they are or may be eligible for Medicaid, be aware of Medicaid coverage options, and be able to easily apply for and enroll in coverage.

¹¹ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

The second dimension of access in this continuum relates to maintaining coverage once the beneficiary is enrolled in the Medicaid program initially. Maintaining coverage requires that eligible beneficiaries are able to stay enrolled in the program without interruption, or that they know how to and can smoothly transition to other health coverage, such as CHIP, Exchange coverage, or Medicare, when they are no longer eligible for Medicaid coverage but have become eligible for other health coverage programs. In September 2022, we published a proposed rule, *Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility, Determination, Enrollment, and Renewal Processes* (87 FR 54760; hereinafter the "Streamlining Eligibility & Enrollment proposed rule") to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, CHIP, and the Basic Health Program (BHP).

The third dimension, which is the focus of this proposed rule, is access to services and supports. This rule is focused on addressing additional critical elements of access: (1) potential access, which refers to a beneficiary's access to providers and services, whether or not the providers or services are used; (2) beneficiary utilization, which refers to beneficiaries' actual use of the providers and services available to them; and (3) beneficiaries' perceptions and experiences with the care they did or were not able to receive. These terms and definitions build upon previous efforts to examine how best to monitor access.¹²

We are engaging in an array of regulatory activities, including three rulemakings that are currently underway (more specifically, the Streamlining Eligibility & Enrollment proposed rule, a proposed rule, entitled Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, on managed care including matters of access, and this proposed rule on access). Additionally, we are taking non-regulatory activities to improve

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¹² Kenney, Genevieve M., Kathy Gifford, Jane Wishner, Vanessa Forsberg, Amanda I. Napoles, and Danielle Pavliv. "Proposed Medicaid Access Measurement and Monitoring Plan." Washington, D.C.: The Urban Institute. August 2016. Accessed at https://www.urban.org/sites/default/files/publication/88081/2001143-medicaid-access-measurement-and-monitoring-plan_0.pdf.

beneficiary access to care (for example, best practices toolkits and technical assistance to States) to improve access to health care services across Medicaid delivery systems.

As noted earlier, we issued the Streamlining Eligibility & Enrollment proposed rule to address the first two dimensions of access to health care: (1) enrollment in coverage and (2) maintenance of coverage. Through that proposed rule, we sought to streamline Medicaid, CHIP and BHP eligibility and enrollment processes, reduce administrative burden on States and applicants/enrollees toward a more seamless eligibility and enrollment process, and increase the enrollment and retention of eligible individuals.

The managed care proposed rule seeks to improve access to care and quality outcomes for Medicaid and CHIP beneficiaries enrolled in managed care by: creating standards for timely access to care and States' monitoring and enforcement efforts; reducing burden for some State directed payments and certain quality reporting requirements; adding new standards that would apply when States use in lieu of services and settings (ILOSs) to promote effective utilization, and specifying the scope and nature of ILOS; specifying medical loss ratio (MLR) requirements, and establishing a quality rating system for Medicaid and CHIP managed care plans.

Through the managed care proposed rule and this proposed rule (Ensuring Access to Medicaid Services), we propose additional requirements to address the third dimension of the health care access continuum: access to services. The proposed requirements outlined later in this section focus on improving access to services in Medicaid by utilizing tools such as FFS rate transparency, standardized reporting for HCBS, and improving the process for interested parties, especially Medicaid beneficiaries, to provide feedback to State Medicaid agencies and for Medicaid agencies to respond to the feedback (also known as a feedback loop).

Through a combination of these three proposed rules, we seek to address a range of access-related challenges that impact how beneficiaries are served by Medicaid across all of its delivery systems. FFP would be available for expenditures that might be necessary to implement

the activities States would need to undertake to comply with the provisions of the proposed rules, if finalized.

Finally, we also believe it is important to acknowledge the role of health equity within this proposed rule. Medicaid plays a disproportionately large role in covering health care for people of color in this country. Consistent with EO 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021), which calls for advancing equity for underserved populations, we are working to ensure our programs consistently provide high-quality care to all beneficiaries, and thus advance health equity, consistent with the goals and objectives we have outlined in the CMS Framework for Health Equity 2022-2032¹⁵ and the HHS Equity Action Plan. That effort includes increasing our understanding of the needs of those we serve to ensure that all individuals have access to equitable care and coverage.

We recognize that each State faces a unique set of challenges related to the resumption of its normal program acvitities after the end of the COVID-19 public health emergency (PHE). More specifically, the expiration of the continuous enrollment condition authorized by the Families First Coronavirus Response Act (FFCRA) presents the single largest health coverage transition event since the first open enrollment period of the Affordable Care Act. As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, States have been required to maintain enrollment of nearly all Medicaid enrollees. This continuous enrollment condition expired on March 31, 2023, and States now have 12 months to initiate and 14 months to complete renewals for all individuals enrolled in Medicaid, CHIP and the Basic Health Program. Additionally, many other temporary authorities adopted by States during the COVID-19 PHE will expire at the end of the PHE, and

¹³ Guth, M and Artiga, S. Medicaid and Racial Health Equity March 2022. Accessed at https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/.

¹⁴ Executive Order 13985: https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

¹⁵ CMS Framework for Health Equity 2022–2032: https://www.cms.gov/files/document/cms-framework-health-equity.pdf.

¹⁶ HHS Equity Action Plan. April 2022. Accessed at https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf.

States will be returning to regular operations across their programs. The resumption of normal Medicaid operations is generally referred to as "unwinding" and the 12-month period for States to initiate all outstanding eligibility actions that were delayed because of the FFCRA continuous enrollment condition is called the "unwinding period." CMS considered States' unwinding responsibilities when proposing the effective dates for the proposals in this rule, but, as noted below, we seek State feedback on whether our proposals strike the correct balance.

As we contemplate the timing of a final rule, we are considering adopting an effective date of 60 days following publication of the final rule and separate compliance dates for various provisions, which we note where relevant in our discussion of specific proposals in this proposed rule. We seek comment on whether an effective date of 60 days following publication would be appropriate when combined with later dates for compliance for some provisions. We also seek comment on the timeframe that would be most achievable and appropriate for compliance with each proposed provision and whether the compliance date should vary by provision.

B. Medical Care Advisory Committees (MCAC)

We obtained feedback during various public engagement activities conducted with States and other interested parties, which supports research findings that the beneficiary perspective and lived Medicaid experience¹⁷ should be considered when making policy decisions related to Medicaid programs.^{18,19} A 2022 report from the HHS Assistant Secretary of Planning and Evaluation (ASPE) noted that including people with lived experience in the policy-making process can lead to a deeper understanding of the conditions affecting certain populations, facilitate identification of possible solutions, and avoid unintended consequences of potential

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¹⁷ Lived experience refers to "representation and understanding of an individual's human experiences, choices, and options and how those factors influence one's perception of knowledge" based on one's own life. In this context, we refer to people who have been enrolled in Medicaid currently or in the past. Accessed at https://aspe.hhs.gov/lived-experience#:~:text=In%20the%20context%20of%20ASPE%E2%80%99s%20research%2C%20people%20with,programs%20th

¹⁸ Zhu JM, Rowland R, Gunn R, Gollust S, Grande DT. Engaging Consumers in Medicaid Program Design: Strategies from the States. Milbank Q. 2021 Mar;99(1):99-125. doi: 10.1111/1468-0009.12492. Epub 2020 Dec 15. PMID: 33320389; PMCID: PMC7984666. Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984666/.

¹⁹ Key Findings from the Medicaid MCO Learning Hub Discussion Group Series and Roundtable – Focus on Member Engagement and the Consumer Voice. NORC at the University of Chicago. Jan 2021. Accessed at https://www.norc.org/PDFs/Medicaid%20Managed%20Care%20Organization%20Learning%20Hub/MMCOLearningHub_MemberEngagement.pdf.

policy or program changes that could negatively impact the people the program aims to serve.²⁰ We have concluded that beneficiary perspectives need to be central to operating a high-quality health coverage program that consistently meets the needs of all its beneficiaries.

However, effective community engagement is not as simple as planning a meeting and requesting feedback. To create opportunities that facilitate true engagement, it is important to understand and honor strengths and assets that exist within communities; recognize and solicit the inclusion of diverse voices; dedicate resources to ensuring that engagement is done in culturally meaningful ways; ensure timelines, planning processes, and resources that support equitable participation; and follow up with communities to let them know how their input was utilized. Ensuring optimal health outcomes for all beneficiaries served by a program through the design, implementation, and operationalization of policies and programs requires intentional and continuous effort to engage people who have historically been excluded from the process.

Section 1902(a)(4) of the Act is a longstanding statutory provision that, as implemented in part in regulations currently codified at 42 CFR 431.12,²¹ requires States to have a Medical Care Advisory Committee (MCAC) in place to advise the State Medicaid agency about health and medical care services. Under section 1903(a)(7) of the Act, expenditures made by the State agency to operate the MCAC are eligible for Federal administrative match.

The current MCAC regulations at § 431.12 require States to establish such a committee, and describe high-level requirements related to the composition of the committee, the scope of topics to be discussed, and the support the Committee can receive from the State in its administration. Due to the lack of specificity in the current regulations, these regulations have not been consistently implemented across States. For example, there is no mention of how States should approach meeting periodicity or meeting structure in ways that are conducive to including a variety of Medicaid interested parties. There is also no mention in the regulations about how

²⁰ Syreeta Skelton-Wilson et al., "Methods and Emerging Strategies to Engage People with Lived Experience," Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, January 4, 2022, https://aspe.hhs.gov/reports/lived-experience-brief.

²¹ The regulatory provision was originally established in 36 FR 3793 at 3870.

States can build accountability through transparency with their interested parties by publicly sharing meeting dates, membership lists, and the outcomes of these meetings. The regulations also limit the MCAC discussions to topics about health and medical care services – which in turn limits the benefits of using the MCAC as a vehicle that can provide States with varied ideas, suggestions, and experiences on a range of issues (medical and non-medical) related to the effective administration of the Medicaid program.

As such, we have determined the requirements governing MCACs need to be more robust to ensure all States are using these committees optimally to realize a more effective and efficient Medicaid program that is informed by the experiences of beneficiaries, their caretakers, and other interested parties. The current regulations have been in place without change for over 40 years.²² Over the last four decades, we have learned that the current MCAC requirements are insufficient in ensuring that the beneficiary perspective is meaningfully represented on the MCAC. Recent research regarding soliciting input from individuals with lived experience, including our recent discussions with States about their MCAC, provide a unique opportunity to re-examine the purpose of this committee and update the policies to reflect four decades of program experience.

In 2022, we gathered feedback from various public engagement activities conducted with States, other interested parties, and directly from a subset of State Medicaid agencies that described a wide variation in how States are operating MCACs today. The feedback suggested that some MCACs operate simply to meet the broad Federal requirements. As discussed previously in this section, we have discovered that our current regulations do not further the statutory goal of meaningfully engaging Medicaid beneficiaries and other low-income people in matters related to the operation of the Medicaid program. Meaningful engagement can help develop relationships and establish trust between the communities served and the Medicaid agency to ensure States receive important information concerning how to best provide health

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²² 43 FR 45091 at 45189.

coverage to their beneficiary populations. The current MCAC regulations establish the importance of broad feedback from interested parties, but they lack the specificity that can ensure States use MCACs in ways that facilitate that feedback.

The current regulation requires that MCACs must include Medicaid beneficiaries as committee members. However, the regulations do not mention or account for the reality that other interested parties can stifle beneficiary contribution in a group setting. For example, when there are a small number of beneficiary representatives in large committees with providers, health plans, and professional advocates, it can be uncomfortable and intimidating for beneficiaries to share their perspective and experience. Based on these reasons, several States already use beneficiary-only groups that feed into larger MCACs.

Improvements to the MCACs are critical to ensuring a robust and accurate understanding of beneficiaries' challenges to health care access. The current regulations value State Medicaid agencies having a way to get feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care, and to assist States in understanding and better addressing those challenges. These committees also represent unique opportunities for States to include representation by members that reflect the demographics of their Medicaid program to ensure that the program is best serving the needs of all beneficiaries, but not all States are utilizing that opportunity.

The proposed rule seeks to strike a balance that reflects how States currently use advisory committees (such as MCACs or standalone beneficiary groups). We know that some States approach these committees as a way to meet a Federal requirement while other States are using them in much more innovative ways. As a middle ground, the proposed rule seeks to: (1) address the gaps in the current regulations described previously in this section; and (2) establish

requirements to implement more effective advisory committees. States would select members in a way that reflects a wide range of Medicaid interested parties (covering a diverse set of populations and interests relevant to the Medicaid program), place a special emphasis on the inclusion of the beneficiary perspective, and create a meeting environment where each voice is empowered to participate equally.

The changes we propose in this rule are rooted in best practices learned from experience and from current State examples of community engagement that support getting the type of feedback and experiences from beneficiaries, their caretakers, providers, and other interested parties that can then be used to positively impact care delivered through the Medicaid program.

Accordingly, the proposed rule includes changes that, if finalized, would support the implementation of the principles of bi-directional feedback, transparency, and accountability. We propose changes to the features of the new committee that could most effectively ensure member engagement, including the staff and logistical support that is required for beneficiaries and individuals representing beneficiaries to meaningfully participate in these committees. We also propose changes to expand the scope of topics to be addressed by the committee, address committee membership composition, prescribe the features of administration of the committee, establish requirements of an annual report, and underscore the importance of beneficiary engagement through the addition of a related beneficiary-only group.

C. Home and Community-Based Services (HCBS)

While Medicaid programs are required to provide medically necessary nursing facility services for most eligible individuals age 21 or older, coverage for home and community-based services (HCBS) is a State option.²³ As a result of this "institutional bias," Medicaid reimbursement for LTSS was primarily spent on institutional care, historically, with very little

²³ Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. "Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019." Chicago, IL: Mathematica, December, 2021. Accessed at https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf.

spending for HCBS.²⁴ However, over the past several decades, States have used several Medicaid authorities,²⁵ as well as CMS-funded grant programs,²⁶ to develop a broad range of HCBS to provide alternatives to institutionalization for eligible Medicaid beneficiaries and to advance person-centered care. Consistent with many beneficiaries' preferences for where they would like to receive their care, HCBS have become a critical component of the Medicaid program and are part of a larger framework of progress toward community integration of older adults and people with disabilities that spans efforts across the Federal government. In fact, total Medicaid HCBS expenditures surpassed the long-standing benchmark of 50 percent of LTSS expenditures in FY 2013 and has remained higher than 50 percent since then, reaching 55.4 percent in FY 2017 and 58.6 percent in FY 2019.²⁷ A total of 30 States spent at least 50 percent of Medicaid LTSS expenditures on HCBS in FY 2019.

Furthermore, HCBS play an important role in States' efforts to achieve compliance with the Americans with Disabilities Act (ADA) of 1990, section 504 of the Rehabilitation Act of 1973 (section 504),²⁸ section 1557 of the Affordable Care Act, and the Supreme Court's decision in *Olmstead v. L.C.*²⁹, in which the Court held that unjustified segregation of persons with disabilities is a form of unlawful discrimination under the ADA³⁰ and States must ensure that

²⁴ Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf.

²⁵ These authorities include Medicaid State plan personal care services and Social Security Act (the Act) section 1915(c) waivers, section 1915(i) State plan HCBS, section 1915(j) self-directed personal assistant services, and section 1915(k) Community First Choice. See https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-authorities/index.html for more information authority under section 1115(a) of the Act to cover and test home and community-based service strategies. See https://www.medicaid.gov/medicaid/section-1115-demonstrations/index.html for more information.

²⁶ Federally funded grant programs include the Money Follows the Person (MFP) demonstration program, which was initially authorized by the Deficit Reduction Act of 2005 (Pub. L. 109-171). The MFP program was recently extended under the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), which allowed new States to join the demonstration and made statutory changes affecting MFP participant eligibility criteria, allowing grantees to provide community transition services under MFP earlier in an eligible individual's inpatient stay.

²⁷ Murray, Caitlin, Alena Tourtellotte, Debra Lipson, and Andrea Wysocki. "Medicaid Long Term Services and Supports Annual Expenditures Report: Federal Fiscal Year 2019." Chicago, IL: Mathematica, December 9, 2021. Accessed at https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf.

²⁸ HHS interprets section 504 and Title II of the ADA similarly regarding the integration mandate and the Department of Justice generally interprets the requirements under section 504 consistently with those under Title II of the ADA.

²⁹ 527 U.S. 581 (1999).

³⁰ Medicaid and the Olmstead Decision. Accessed at https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688.

persons with disabilities are served in the most integrated setting appropriate to their needs.³¹ Section 9817 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117-2) recently provided a historic investment in Medicaid HCBS by providing qualifying States with a temporary 10 percentage point increase to the FMAP for certain Medicaid expenditures for HCBS that States must use to implement or supplement the implementation of one or more activities to enhance, expand, or strengthen HCBS under the Medicaid program.³²

Medicaid coverage of HCBS varies by State and can include a combination of medical and non-medical services, such as case management, homemaker, personal care, adult day health, habilitation (both day and residential), and respite care services. HCBS programs serve a variety of targeted population groups, such as older adults, and children and adults with intellectual or developmental disabilities, physical disabilities, mental health/substance use disorders, and complex medical needs. HCBS programs provide opportunities for Medicaid beneficiaries to receive services in their own homes and communities rather than in institutions.

CMS and States have worked for decades to support the increased availability and provision of high-quality HCBS for Medicaid beneficiaries. While there are quality and reporting requirements for Medicaid HCBS, the requirements vary across authorities and are often inadequate to provide the necessary information for ensuring that HCBS are provided in a high-quality manner that best protects the health and welfare of beneficiaries. Consequently, quality measurement and reporting expectations are not consistent across and within services, but instead vary depending on the authorities under which States are delivering services.

Additionally, States have flexibility to determine the quality measures they use in their HCBS programs. While we support State flexibility, a lack of standardization has resulted in thousands of metrics and measures currently in use across States, with different metrics and measures often

³¹ Medicaid and the Olmstead Decision. Accessed at https://www.medicaid.gov/about-us/program-history/medicaid-50th-anniversary/entry/47688.

³² Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at https://www.medicaid.gov/medicaid/home-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.

used for different HCBS programs within the same State. As a result, CMS and States are limited in the ability to compare HCBS quality and outcomes within and across States or to compare the performance of HCBS programs for different populations.

In addition, although there are differences in rates of disability among demographic groups, there are very limited data currently available to assess disparities in HCBS access, utilization, quality, and outcomes. Few States have the data infrastructure to systematically or routinely report data that could be used to assess whether disparities exist in HCBS programs. This lack of available data also prevents CMS and States from implementing interventions to make improvements in HCBS programs designed to consistently meet the needs of all beneficiaries.

Compounding these concerns have been notable and high-profile instances of abuse and neglect in recent years, which have been shown to result from poor quality care and inadequate oversight of HCBS in Medicaid. For example, a 2018 report, "Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight," "33" ("Joint Report"), which was jointly developed by the US Department of Health and Human Services' Administration for Community Living (ACL), Office for Civil Rights (OCR), and the Office of Inspector General (OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm. In addition, while existing regulations provide safeguards for all Medicaid beneficiaries in the event of a denial of Medicaid eligibility or an adverse benefit determination by the State Medicaid agency and, where applicable, by the beneficiary's managed care plan, there are no safeguards related to other issues that HCBS beneficiaries may experience, such as the failure of a provider to comply with the HCBS settings requirements or difficulty accessing the services in the person-centered

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³³ Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes-joint-report.pdf.

service plan unless the individual is receiving those services through a Medicaid managed care arrangement.

Finally, through our regular interactions with State Medicaid agencies, provider groups, and beneficiary advocates, we observed that all these interested parties routinely cite a shortage of direct care workers and high rates of turnover in direct care workers among the greatest challenges in ensuring access to high-quality, cost-effective HCBS for people with disabilities and older adults. Some States have also indicated that a lack of direct care workers is preventing them from transitioning individuals from institutions to home and community-based settings.

While workforce shortages have existed for years, they have been exacerbated by the COVID-19 pandemic, which has resulted in higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID-19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in types of retail and other jobs that tend to draw from the same pool of workers. 34,35,36

To address the list of challenges outlined in this section, we are proposing new Federal requirements in this proposed rule to improve access to care, quality of care, and health and quality of life outcomes; promote health equity for people receiving Medicaid-covered HCBS; and ensure that there are safeguards in place for beneficiaries who receive HCBS through FFS delivery systems. We seek comment on other areas for rulemaking consideration. The proposed requirements are also intended to promote public transparency related to the administration of Medicaid HCBS programs.

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³⁴ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.

³⁵ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf. ³⁶ American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at

https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

D. Fee-For-Service (FFS) Payment

Section 1902(a)(30)(A) of the Act requires States to "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." Regulations at § 447.203 require States to develop and submit to CMS an access monitoring review plan (AMRP) for a core set of services. Currently, the regulations rely on available State data to support a determination that the State's payment rates are sufficient to ensure access to care in Medicaid FFS that is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required under section 1902(a)(30)(A) of the Act.

In the May 6, 2011, Federal Register, we published the "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services" proposed rule (76 FR 26341; hereinafter "2011 proposed rule"), which outlined a data-driven process for States with Medicaid services paid through a State plan under FFS to follow in order to document their compliance with section 1902(a)(30)(A) of the Act. We finalized the 2011 proposed rule in the November 2, 2015, Federal Register when we published the "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services" final rule with comment period (80 FR 67576; hereinafter "2015 final rule with comment period"). Among other requirements, the 2015 final rule with comment period required States to develop and submit to CMS an AMRP for certain Medicaid services that is updated at least every 3 years. Additionally, the rule required that when States submit a SPA to reduce or restructure provider payment rates, they must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed reduction or restructuring of Medicaid FFS payment rates on beneficiary access to care. We published the "Medicaid Program; Deadline for Access Monitoring Review Plan Submissions" final rule in the April 12, 2016 Federal Register

(81 FR 21479; hereinafter "2016 final rule") with a revised deadline for States' AMRPs to be submitted to us.

Following enactment, numerous States have expressed concern regarding the administrative burden associated with the 2015 final rule with comment period requirements, especially those States with high rates of beneficiary enrollment in managed care. In an attempt to address some of the States' concerns regarding unnecessary administrative burden, we issued a State Medicaid Director letter (SMDL) on November 16, 2017 (SMDL #17-004), which clarified the circumstances in which provider payment reductions or restructurings would likely not result in diminished access to care, and therefore, would not require additional analysis and monitoring procedures described in the 2015 final rule with comment period.³⁷ Subsequently, in the March 23, 2018 Federal Register, we published the "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold" proposed rule (83 FR 12696; hereinafter "2018 proposed rule"), which would have exempted States from requirements to analyze certain data or monitor access when the vast majority of their covered beneficiaries receive services through managed care plans. That proposed rule, if it had been finalized, would have provided similar flexibility to all States when they make nominal rate reductions or restructurings to FFS payment rates. Based on the responses received during the public comment period, we decided not to finalize the proposed exemptions.

In the July 15, 2019 **Federal Register**, we published the "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission" proposed rule (84 FR 33722; hereinafter "2019 proposed rule") to rescind the regulatory access requirements at §§ 447.203(b) and 447.204, and concurrently issued a CMCS Informational Bulletin³⁸ stating the agency's intention to establish a new access strategy. Based on the responses we received during the

³⁷ State Medicaid Director Letter #17-0004 Re: Medicaid Access to Care Implementation Guidance. Accessed at https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf (November 2017).

³⁸ CMCS Informational Bulletin: Comprehensive Strategy for Monitoring Access in Medicaid, Accessed at https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf (July 2019).

public comment period, we decided not to finalize the 2019 proposed rule, and instead continue our efforts and commitment to develop a data-driven strategy to understand access to care in the Medicaid program.

States have continued to question whether the AMRP process is the most effective or accurate reflection of access to care in a State's Medicaid program, and requested we provide additional clarity on the data necessary to support compliance with section 1902(a)(30)(A) of the Act. In reviewing the information that States presented through the AMRPs, we also have questioned whether the data and analysis consistently address the primary access-related question posed by section 1902(a)(30)(A) of the Act -- namely, whether rates are sufficient to ensure access to care at least as great as that enjoyed by the general population in geographic areas. The unstandardized nature of the AMRPs, which largely defer to States to determine appropriate data measures to review and monitor when documenting access to care, have made it difficult to assess whether any single State's analysis demonstrates compliance with section 1902(a)(30)(A) of the Act.

While the AMRPs were intended to be a useful guide to States in the overall process to monitor beneficiary access, they are generally limited to access in FFS delivery systems and focus on targeted payment rate changes rather than the availability of care more generally or population health outcomes (which may be indicative of the population's ability to access care). Moreover, the AMRP processes are largely procedural in nature and not targeted to specific services for which access may be of particular concern, requiring States to engage in triennial reviews of access to care for certain broad categories of Medicaid services – primary care services, physician specialist services, behavioral health services, pre and post-natal obstetric services, and home health services. Although the 2016 final rule reasonably discussed that the selected service categories intended to be indicators for available access in the overall Medicaid FFS system, the categories do not easily translate to the services authorized under section 1905(a) of the Act, granting States deference as to how broadly or narrowly to apply the AMRP

analysis to services within their programs. For example, the category "primary care services" could encompass several of the Medicaid service categories described within section 1905(a) of the Act and, without clear guidance on which section 1905(a) services categories, qualified providers, or procedures we intended States to include within the AMRP analyses. States were left to make their own interpretations in analyzing access to care under the 2016 final rule.

Similarly, a number of the AMRP data elements, both required and suggested within the 2016 final rule, may be overly broad, subject to interpretation, or difficult to obtain. Specifically, under the 2016 final rule provisions, States are required to review: the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Though service utilization and provider participation are relatively easy measures to source and track using existing Medicaid program data, an analysis of whether beneficiary needs are fully met is at least somewhat subjective and could require States to engage in a survey process to complete. Additionally, while most Medicaid services have some level of equivalent payment data that can be compared to other available public payer data, such as Medicare, private pay information may be proprietary and difficult to obtain. Therefore, many States struggled to meet the regulatory requirement comparing Medicaid program rates to private payer rates because of their inability to obtain private payer data.

Due to these issues, States produced varied AMRPs through the triennial process that were, as a whole, difficult to interpret or to use in assessing compliance with section 1902(a)(30)(A) of the Act. In isolation, a State's specific AMRP most often presented data that could be meaningful as a benchmark against changes within a State's Medicaid

program, but did not present a case for Medicaid access consistent with the general population in geographic areas. Frequently, the data and information within the AMRPs were presented without a formal determination or attestation from the State that the information presented established compliance with section 1902(a)(30)(A) of the Act. Because the States' AMRPs generally varied to such a great degree, there was also little to glean in making State-to-State comparisons of performance on access measures, even for States with geographic and demographic similarities.

Based on results of the triennial AMRPs, we were uncertain of how to make use of the information presented within them other than to make them publicly available. We published the AMRPs on Medicaid.gov but had little engagement with States on the content or results of the AMRPs since much of the information within the plans could not meaningfully answer whether access in Medicaid programs satisfied the requirements of section 1902(a)(30)(A) of the Act. Additionally, we received little feedback from providers, beneficiaries, or advocates on whether or how interested parties made use of the triennial AMRPs. However, portions of the 2016 final rule related to public awareness and feedback on changes to Medicaid payment rates and the analysis that we received from individual States proposing to make rate changes was of great benefit in determining approvals of State payment change proposals. Specifically, the portion of the AMRP process where States update their plans to describe data and measures to serve as a baseline against which they monitor after reducing or restructuring Medicaid payments allows States to document consistency with section 1902(a)(30)(A) of the Act at the time of SPA submission, usually as an assessment of how closely rates align with Medicare rates, and to understand the impact of reductions through data monitoring after SPA approval.

Under this proposed rule, we are proposing to balance elimination of unnecessary Federal and State administrative burden with robust implementation of the Federal and State shared obligation to ensure that Medicaid payment rates are set at levels sufficient to ensure access to care for beneficiaries consistent with section 1902(a)(30)(A) of the Act. The provisions of this

proposed rule, as discussed in more detail later, would better achieve this balance through improved transparency of Medicaid FFS payment rates, through publication of a comparative payment rate analysis to Medicare and payment rate disclosures, and through a more targeted and defined approach to evaluating data and information when States propose to reduce or restructure their Medicaid payment rates. Payment rate transparency is a critical component of assessing compliance with section 1902(a)(30)(A) of the Act. In addition, payment rate transparency helps to ensure that interested parties have basic information available to them to understand Medicaid payment levels and the associated effects of payment rates on access to care so that they may raise concerns to State Medicaid agencies via the various forms of public processes discussed within this proposed rule. Along with improved payment rate transparency and disclosures as well as comparative payment rate analyses, we are proposing a more efficient process for States to undertake when submitting rate reduction or restructuring SPAs to CMS for review. As we move toward aligning our Medicaid access to care strategy across FFS and managed care delivery systems, we will consider additional rulemaking to help ensure that Medicaid payment rate information is appropriately transparent and rates are fully consistent with broad access to care across delivery systems, so that interested parties have a more complete understanding of Medicaid payment rate levels and resulting access to care for beneficiaries.

II. Provisions of the Proposed Regulations

A. Medicaid Advisory Committee and Beneficiary Advisory Group (§ 431.12)

Current § 431.12 requires States to have a MCAC to advise the State Medicaid agency about health and medical care services. The current regulations are intended to ensure that State Medicaid agencies have a way to receive feedback from interested parties on issues related to the Medicaid program. However, the current regulations lack specificity related to how these committees can be used to ensure the proper and efficient administration of the Medicaid program more expressly by more fully promoting beneficiary perspectives.

Under the authority of section 1902(a)(4) of the Act, section 1902(a)(19) of the Act, and our general rulemaking authority in section 1102 of the Act, we propose to update § 431.12 to replace the current MCAC requirements with a committee framework designed to ensure the proper and efficient administration of the Medicaid program and to better ensure that care and services under the Medicaid program will be provided in a manner consistent with the best interests of the beneficiaries. If finalized, States would be required to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Group (BAG). The MAC and its corresponding BAG would serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program. With this proposal, FFP, or Federal match, for Medicaid administrative activities would remain available to States for expenditures related to MAC and BAG activities in the same manner as the former MCAC.

We propose to amend the title and paragraph (a) of § 431.12 to update the name of the existing MCAC to the MAC, and to add the requirement for States to establish and operate a dedicated advisory group comprised of Medicaid beneficiaries, the BAG. Our goal is that the committee and its corresponding advisory group would advise the State not only on issues related to health and medical services, as the MCAC did, but also on matters related to policy development and to the effective administration of the Medicaid program consistent with the language of section1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. While the Medicaid program covers medical services, the program is increasingly also covering services designed to address beneficiaries' social determinants of health and their health-related social needs more generally. Therefore, having a discussion with the MAC about topics that are not directly related to covered services may be necessary to ensure that beneficiaries are able to meaningfully access these services. Expanding the scope of the current committee is necessary to align the actions of the committee with the expanding scope of the Medicaid program,

consistent with section 1902(a)(4)(B) of the Act, because the MAC creates a formalized way for interested parties and beneficiary representatives to provide feedback to the State about issues related to the Medicaid program and the services it covers and to help ensure that the program operates efficiently and as it was designed to operate.

Every State will vary in the types of topics that would benefit from the interested parties' feedback, so discretion on which topics will be discussed with the MAC will be left to the State. Depending on the priorities of the State in a given year, States may find it helpful to bring to the MAC issues related to, for example, grievances, consumer experience survey ratings, design of a new program, or other like topics. Proposed mandates for these entities are described later in this section under proposed paragraph (g). We further propose conforming updates to paragraph (b) regarding the State plan requirements, to reflect the proposed MAC and BAG and the expanded mandate proposed in this proposed rule. The interested parties advisory group, proposed and described in the FFS sections of this proposed rule, to advise States on rate setting for certain HCBS is not related to the MAC or BAG outlined here. We note in that section that a State would be able utilize its MAC and BAG to provide recommendations for payment rates, thereby satisfying the requirements of that proposal. However, the MAC and BAG requirements proposed here, if finalized, are wholly separate from the interested parties advisory group, regardless of whether that proposal is finalized as well.

We propose to update paragraph (c) of § 431.12 regarding appointment of committee members to specify that the members of the MAC and BAG must be appointed by the agency director or higher State authority on a rotating, continuous basis. Under our proposals, committee and advisory group members would serve a specific amount of time, the length of which will be determined by each State and noted in its bylaws. After a committee or advisory group member term has been completed, the State will appoint a new member, thus ensuring that MAC and BAG memberships rotate continuously. We propose the State be required to make public its process and bylaws for recruitment and appointment of members of the MAC and

BAG and post the list of both sets of members on the State's website. Under our proposal, the website page where this information is located must be easily accessible by the public. These updates align with how advisory committees similar to the MAC and BAG are run, and the changes are designed to provide additional details to support States' operation of the MAC and BAG. Further, these updates facilitate transparency, improving the current regulations, which do not mention nor promote transparency of information related the MCAC with the public. We believe that transparency of information can lead to enhanced accountability on the part of the State to making its MAC and BAG as effective as possible.

Advisory committees and groups can be most effective when they represent a wide range of perspectives and experiences. The current MAC regulations only provide high level descriptions of types of members that should be selected. Since we know that each State environment is different, in the proposed rule, we continue to provide the State with discretion on how large the MAC and BAG should be, but we outline in more detail the types of categories of members that can best reflect the needs of a Medicaid program. We believe that diversely populated MACs and BAGs can provide States with access to a broad range of perspectives, and importantly, beneficiaries' perspective, which can positively impact the administration of the Medicaid program.

We encourage States to take into consideration, as part of their member selection process, the demographics of the Medicaid population in their State. Keeping diverse representation in mind as a goal for the MAC membership can be a way for States to acknowledge that specific populations and those receiving critically important services be appropriately represented on the MAC. For example, in making the MAC appointments, the State may want to balance the representation of the MAC according to geographic areas of the State and the demographics of the Medicaid program of the State. The State may want to consider geographical diversity (for example, urban, rural, tribal) when making its membership selections. The State could also consider demographic representation of its membership by including members representing or

serving Medicaid beneficiaries the following categories: (1) children's health care; (2) behavioral health services; (3) preventive care and reproductive health services; (4) health or service issues pertaining specifically to people over age 65; and (5) health or service issues pertaining specifically to people with disabilities. By offering these considerations, we seek to support States in their efforts to eliminate differences in health care access and outcomes experienced by diverse populations enrolled in Medicaid. Our aim is to support several of the priorities for operationalizing health equity across CMS programs as outlined in the CMS Framework for Health Equity (2022-2032) and the HHS Equity Action Plan which is consistent with EO 13985 which calls for advancing equity for underserved populations.

As we considered effective ways to better integrate the beneficiary perspective into decisions related the Medicaid program, we also recognized that a diverse and representative set of interested parties should be reflected in the composition of each State's MAC. We propose to amend paragraph (d) of § 431.12 regarding committee membership to account for both membership and composition, and to require the MAC membership include members from the BAG, described later in this section, who are currently or have been Medicaid beneficiaries, and individuals with direct experience supporting Medicaid beneficiaries (for example, family members or caregivers³⁹ of those enrolled in Medicaid); as well as advocacy groups; providers or administrators of Medicaid services; representatives of managed care plans or State health plan associations representing such managed care plans; and representatives from other State agencies that serve Medicaid beneficiaries. This proposal is consistent with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan. The change we propose would support States to set up MACs that align with section 1902(a)(4)(B) of the Act since they would now have to select the membership composition to reflect the community members who represent the interests of Medicaid beneficiaries. The State also benefits from

³⁹ Caregivers can be paid or unpaid.

having a way to hear how the Medicaid program can be responsive to its beneficiaries' and the Medicaid community's needs.

Specifically, in paragraph (d)(1) of § 431.12, we propose that at least 25 percent of the MAC must be individuals with lived Medicaid beneficiary experience from the BAG. This means that the BAG would be comprised of people who: (1) are currently or have been Medicaid beneficiaries and (2) individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid). We selected 25 percent as a threshold to reflect the importance of including the beneficiary perspective in the administration of the Medicaid program and to ensure that the beneficiary perspective has equitable representation in the feedback provided by the MAC. We did not select a higher percentage because we acknowledge that States will benefit from a MAC that includes representation from a diverse set of interested parties who work in areas related to Medicaid but are not beneficiaries, their family members or their caregivers. We seek comment on the 25 percent requirement.

As noted earlier, representation from the remaining committee members would be left to the States' discretion. Rather than prescribing specific percentages for each category, we only propose to require representation from each category as part of the MAC. The specific percentage of each of category (other than the BAG members) relative to the whole committee can be determined by each State. This approach would provide States with flexibility to determine how to best represent the unique landscape of each State's Medicaid program. We seek comment on what should be the minimum percentage requirement that MAC members be current/past Medicaid beneficiaries or individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers of those enrolled in Medicaid).

States need to know how to deliver care to its beneficiaries. In addition to hearing directly from beneficiaries, the State can gain insights into how to effectively administer its program, from other groups of the Medicaid community. Categorically, we propose in paragraph (d)(2) that the rest of the MAC must include representation from each category: (1) members of

State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries; (2) clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care; (3) representatives from participating Medicaid managed care plans or the State health plan association representing such plans, as applicable; and (4) representatives from other State agencies serving Medicaid beneficiaries, as ex-officio members.

States are determining which types of providers to include under the clinical providers or administrators category, we recommend they consider a wide range of providers or administrators that are experienced with the Medicaid program including, but not limited to: (1) primary care providers (internal or family medicine physicians or nurse practitioners or physician assistants that practice primary care); (2) behavioral health providers (that is, mental health and substance use disorder providers); (3) reproductive health service providers, including maternal health providers; (4) pediatric providers; (5) dental and oral health providers; (6) community health, rural health clinic or Federally Qualified Health Center (FQHC) administrators; (7) individuals providing long-term care services and supports; and (8) direct care workers⁴⁰ who can be individuals with direct experience supporting Medicaid beneficiaries (such as family members or caregivers). Direct care workers also include community health workers who assist Medicaid beneficiaries in navigating access to needed services and care managers, care coordinators, or service coordinators who assist Medicaid beneficiaries with complex care needs.

We have also identified health plans as an important contributor to the MAC, but we acknowledge that not all States that have managed care delivery systems. We know many

⁴⁰ CMS defines direct care workers as: a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving home and community-based services; (2) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; (3) A direct support professional; (4) A personal care attendant; (5) A home health aide; or (6) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid-eligible individuals receiving home and community-based services.

Medicaid health plans administer similar committees and thus allow for States to tailor health plan representation based on its managed care market. For example, States can fulfil this category with only one or with multiple plans operating in the State. In addition, we also give States the flexibility to meet the health plan representation requirements with either participating Medicaid managed care plans or the State health plan association representing such plans, as applicable.

The proposed language in paragraph (d)(2)(D) broadens the type of representatives from other State agencies that are required to be on the committee from the similar MCAC requirement. The current MCAC regulation requires membership by "the director of the public welfare department or the public health department, whichever does not head the Medicaid agency." By expanding the definition of external agency representation to be broader than the welfare or public health department, we would give States more flexibility in representing the Medicaid program's interests based on States' unique circumstances and organizational structure. States can work with sister State agencies to determine who should participate in the MAC (for example, foster care agency, mental health agency, department of public health). We also propose that these representatives be part of the committee as ex-officio members, not as full members of the MAC. While we believe it will be essential to have these State-interested parties present for program coordination and information-sharing, we believe the formal representation of the MAC should be comprised of beneficiaries, advocates, community organizations, and providers that serve Medicaid beneficiaries.

We propose to replace paragraph (e) of § 431.12; in paragraph (e) to require that States create a BAG, a dedicated beneficiary advisory group that will meet separately from the MAC. Currently, the requirements governing MCACs require the presence of beneficiaries in committee membership but do little to ensure their contributions are considered or their voices heard. For example, current paragraph (e) describes committee participation and requires the committee "[further] the participation of beneficiary members in the agency program." This

requirement provides little guidance toward this goal and creates an environment where a beneficiary may not feel comfortable participating despite the opportunity being afforded in its technical sense. We believe adding the creation of the BAG will result in providing the State with increased access to the beneficiary perspective. This proposal directly addresses and provides the mechanism (the BAG) through which States can meet the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan.

As such, the creation of a separate beneficiary-only advisory group aligns with what we learned from multiple interviews with State Medicaid agencies and other Medicaid interested parties (for example, Medicaid researchers, former Medicaid officials) conducted over the course of 2022 on the effective operation of the existing MCACs. Interested parties described the importance of having a comfortable, supportive, and trusting environment that facilitates beneficiaries' ability to speak freely on matters most important to them. It is equally important that the BAG have a subset of its members that also sit on the State's MAC to ensure that the beneficiary perspective and experience are heard directly. We noted earlier that some States may already have highly effective BAG-type groups operating as part of their Medicaid program. These groups may represent specific constituencies such as children with complex medical needs or older adults or may be participants in a specific waiver. In these instances, States may utilize these groups to satisfy the proposed requirements of this rule, provided the BAG-type group membership includes the MAC members described in paragraph (d)(1). Those States must appoint members from the BAG-type group to serve on the MAC to facilitate this crossover.

Specifically, at paragraph (e)(1), we propose that the MAC members described in proposed paragraph (d)(1) must also be members of the BAG. This proposed requirement would facilitate the bi-directional communication essential to effective beneficiary engagement and allow for meaningful representation of diverse voices across the MAC and BAG. In paragraph (e)(2), we propose that the BAG meetings occur in advance of each MAC meeting to ensure

BAG member preparation for each MAC discussion. BAG meetings would also be subject to requirements we propose in paragraph (f)(5), described later in this section, that the BAG meetings must occur virtually, in-person, or through a hybrid option to maximize member attendance. We plan to expound on best practices for engaging beneficiary participation in committees like the MAC in future guidance.

We propose at subsection (f) an administrative framework for the MAC and BAG to ensure transparency and a meaningful feedback loop to the public and among the members of the committee and group. Interested parties' feedback and recent reports^{41,42} published on meaningful beneficiary engagement illuminate the need for more transparent and standardized processes across States to drive participation from key interested parties and to facilitate the opportunity for participation from a diverse set of members and the community. Further, we believe that in order for the State to comply with the language of section 1902(a)(4)(B) of the Act, which requires a State plan to meaningfully engage Medicaid beneficiaries and other low-income people in the administration of the plan, it needs to be responsive to the needs of its beneficiaries. To be responsive to the needs of its beneficiaries, the State needs to be able to gather feedback from a variety of people that touch the Medicaid program, and the MAC and BAG will serve as the vehicle through which States can obtain this feedback.

Specifically, in paragraph (f)(1), we propose to require State agencies to develop and post publicly on their website bylaws for governance of the MAC and BAG, current lists of MAC and BAG memberships, and past meeting minutes for both the committee and group. In paragraph (f)(2), we propose to require State agencies to develop and post publicly a process for MAC and BAG member recruitment and appointment, and for selection of MAC and BAG leadership. In

⁴¹ Resources for Integrated Care and Community Catalyst, "Listening to the Voices of Dually Eligible Beneficiaries: Successful Member Advisory Councils", 2019. Retrieved from

https://www.resourcesforintegratedcare.com/listening to voices of dually eligible beneficiaries/.

⁴² Centers for Medicare & Medicaid Services.(n.d.). Person & Family Engagement Strategy: Sharing with Our Partners. Retrieved from: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/QualityInitiativesGenInfo/Downloads/Person-and-Family-Engagement-Strategic-Plan-12-12-

^{16.}pdf#:~:text=person%E2%80%99s%20priorities%2C%20goals%2C%20needs%20and%20values.%E2%80%9D%20Using%20these,to%20guide%20all%20clinical%20decisions%20and%20drives%20genuine.

paragraph (f)(3), we propose to require State agencies to develop, publicly post, and implement a regular meeting schedule for the MAC and BAG. The requirement specifies the MAC and BAG must each meet at least once per quarter and hold off-cycle meetings as needed. In paragraph (f)(4), we propose that, at least two MAC meetings per year must be opened to the public. For the MAC meetings that are open to the public, the meeting agenda must include a dedicated time for public comment to be heard by the MAC. Further, the State must also adequately notify the public of the date, location, and time of these type (public) of MAC meetings at least 30 calendar days in advance. None of the BAG meetings are not required to be open to the public, unless the State's BAG members decide otherwise. The same requirements would apply to States whose BAG meetings were determined, by its membership, to be open to the public. We seek comment on this approach.

In paragraph (f)(5), we propose to require that States offer in-person and virtual attendance options to maximize member participation at MAC and BAG meetings. We acknowledge that interested parties may face a range of technological and internet accessibility limitations, and that at a minimum, States will need to provide a telephone dial-in option for MAC and BAG meetings. While we understand that in-person interaction can sometimes assist in building trusted relationships, we also recognize that accommodations for members and the public to participate virtually is important, particularly since the beginning of the COVID-19 pandemic. We invite comment on ways to best strike this balance. We address technical and logistical challenges in paragraph (f)(5) and address effective communication and language access and meeting accessibility in subsequent paragraphs.

With respect to in-person meetings, we propose in paragraph (f)(6) to require that States ensure meeting times and locations for MAC and BAG meetings are selected to maximize participant attendance, which may vary by meeting. For example, States may determine, by consulting with its MAC and BAG members that holding meetings in various locations throughout the State may result in better attendance. In addition, they may ask the committee

and group members about which times and weekdays may be more favorable than others and hold meetings at those times accordingly. States must also use the publicly posted meeting minutes, which lists attendance by members, as a way to gauge which meeting times and locations garner maximum participate attendance. Finally, in paragraph (f)(7), we propose to require State agencies to facilitate participation of beneficiaries by ensuring that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, that communication with individuals with disabilities is as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

We propose to revise paragraph (g) to detail an expansion of the topics on which the MAC and BAG should provide feedback to the Medicaid agency from the prior MCAC requirements. In researching other States' MACs, we know that some already use the MACs to get feedback from interested parties, including beneficiaries, on a variety of topics relating to the effective and efficient administration of the Medicaid program. The changes we propose aim to strike a balance that reflects some States' current practices without putting strict limitations on specific topics for discussion to all States. Broadening the scope of the topics that the MAC and BAG discuss will benefit the State by giving greater insight into how it is currently delivering care for its beneficiaries and thereby assist in identifying ways to improve the way the Medicaid program is administered.

The State will use this engagement with the MAC and BAG to ensure that the beneficiary and interested parties' voices are considered and to allow the opportunity to adjust course based on the feedback provided by the committee and group members. Topics of discussion are to be based on State need and determined in collaboration with the MAC to address matters related to

policy development and matters related to the effective administration of the Medicaid program. These topics could include new policy or program developments; changes to services; coordination of care and quality of services; eligibility, enrollment, and renewal processes; the review of communications to beneficiaries by the State Medicaid agency and Medicaid managed care plans; the provision of culturally and linguistically appropriate services, health equity, disparities, and biases in the Medicaid program; and other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as identified by the MAC, the BAG, or the State.

We propose new paragraph (h) to expand on existing State responsibilities for managing the MAC and BAG regarding staff assistance, participation, and financial support. We understand from States and other interested parties, that many States already provide staffing and financial support to their MACs in ways that meet or going beyond what we propose through our updated requirements. We believe that expanding upon the current standards regarding State responsibility for planning and executing the functions of the MAC and BAG will ensure consistent and ongoing standards to further beneficiaries' and interested parties' engagement. For example, we know that when any kind of interested parties group meets, all members of that group need to fully understand the topics being discussed in order to meaningfully engage in that discussion. This is particularly relevant when the topics of discussion are complex or based in specific terminology as Medicaid related issues often can be.

We believe that when States provide their MACs and BAGs with additional staffing support that can explain, provide background materials, and meet with the members in preparation for the larger discussions, the members have a greater chance to provide more meaningful feedback and ensure that members are adequately prepared to engage in these discussions. The proposed changes to the requirements seek to create environments that support meaningful engagement by the members of these groups whose feedback can then be used by States to support the efficient administration of their Medicaid program. We anticipate providing

additional guidance on model practices, recruitment strategies, and ways to facilitate beneficiary participation, and we invite comments on effective strategies to ensure meaningful interested parties' engagement that in turn can facilitate full beneficiary participation.

Under the current MCAC regulations in § 431.12(f), each State is required to provide the committee with staff assistance from the agency, independent technical assistance as needed to enable it to make effective recommendations, and financial arrangements, if necessary, to make possible the participation of beneficiary members. The changes we propose include adding requirements regarding recruitment, meeting scheduling, recordkeeping, and support for beneficiary members. The overlap with the current regulation would mean much of the work to implement our proposals, if finalized, would already be occurring.

The proposed requirement for beneficiary support, including financial support, is similar to current requirements, such as using dedicated staff to support beneficiary attendance at both the MAC and BAG meetings and providing financial assistance to facilitate meeting attendance by beneficiary members, as needed. Staff may support beneficiary attendance through outreach to the Medicaid beneficiary MAC and BAG members throughout the membership period to provide information and answer questions; identify barriers and supports needed to facilitate attendance at MAC and BAG meetings; and facilitate access to those supports. We are not proposing changes to existing financial support requirements. However, we are proposing an additional requirement that at least one member of the State agency's executive staff attend all MAC and BAG meetings to provide an opportunity for beneficiaries and representatives of the State's leadership to interact directly.

In the spirit of transparency and to ensure compliance with the updated regulations, we propose new paragraph (i) to require that the MAC, with support from the State and in accordance with the requirements proposed at this section, submit an annual report to the State. The BAG perspective and feedback will be embedded in the report, since the Group is represented on the MAC. The State, in turn, would be required to review the report and include

responses to recommendations in the report. Prior to finalizing the report, the State must allow the MAC to perform a final review. Once the MAC completes its final review, the State must publish it by posting it on its website. The proposed requirements of this section seek to both ensure transparency while also facilitating a feedback loop and view into the impact of the committee and group's recommendations. We invite comment on additional ways to ensure that the State can create a feedback loop with the MAC and BAG.

Finally, we propose no changes to, and thus maintain, the current regulatory language on FFP from current paragraph (g) to support committee and group administration, to appear in new paragraph (j) with conforming edits for new committee and group names.

This requirement, if finalized, would be effective 60 days after the effective date of the final rule, which would provide States with 1 year to implement these requirements. We seek comment on whether 1 year is too much or not enough time for States to implement the updates in this regulation in an effective manner. We understand that States may need to modify their current MCACs to reflect the updated requirements and may also need to create the BAG and recruit members to participate, if they do not already have a similar entity already in place.

B. Home and Community-Based Services (HCBS)

We are proposing both to amend and add new Federal HCBS requirements to improve access to care, quality of care, and beneficiary health and quality of life outcomes, while consistently meeting the needs of all beneficiaries receiving Medicaid-covered HCBS. This preamble discusses our proposed changes in the context of current law.

We have previously received questions from States with demonstration projects under section 1115 of the Act that include HCBS about the applicability of other HCBS regulatory requirements. As a result, we are identifying that, consistent with the applicability of other HCBS regulatory requirements to such demonstration projects, the proposed requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services included in this proposed rule, if finalized, would apply to such services included in approved section 1115

demonstration projects, unless we explicitly waive one or more of the requirements as part of the approval of the demonstration project. We are not proposing to apply the requirements for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services in this proposed rule to the Program of All-Inclusive Care of the Elderly (PACE) authorized under sections 1894 and 1934 of the Act, as the existing requirements for PACE either already address or exceed the requirements outlined in this proposed rule, or are substantially different from those for section 1915(c) waiver programs and section 1915(i), (j), and (k) State plan services.

1. Person-Centered Service Plans (42 CFR 441.301(c), 441.450(c), 441.540(c), and 441.725(c))

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as "personcentered service plans" or "service plans"). Existing Federal regulations at § 441.301(c) address the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised, upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs⁴³ (hereinafter the "2014 guidance") that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G, through six assurances, including assurances related to person-centered service plans. The 2014 guidance indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. The six assurances identified in the 2014 guidance were the following:

⁴³ Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf.

- 1. Level of Care: The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facility for Individuals with Intellectual Disabilities;
- 2. Service Plan: The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants;
- 3. Qualified Providers: The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers;
- 4. Health and Welfare: The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare;
- 5. Financial Accountability: The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program; and
- 6. Administrative Authority: The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.⁴⁴

We are proposing a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around service plans. The proposed approach is based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through the RFI⁴⁵ discussed earlier about the need to standardize reporting and set minimum standards for HCBS. Accordingly, the proposed HCBS requirements in this rulemaking are intended to establish a new strategy for

⁴⁴ Performance measures were required for delegated functions unless the delegated functions were covered by performance measures associated with other assurances.

⁴⁵ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

oversight, monitoring, quality assurance, and quality improvement for section 1915(c) waiver programs. The proposed approach focuses on priority areas that have been identified by States, oversight entities, consumer advocacy organizations, and other interested parties. The priority areas are person-centered planning, health and welfare, access, beneficiary protections, and quality improvement. As part of this approach, we propose to establish new minimum performance requirements and new reporting requirements for section 1915(c) waiver programs that are intended to supersede and fully replace the reporting requirements and the 86 percent performance level threshold for performance measures described in the 2014 guidance. Further, to ensure consistency and alignment across HCBS authorities, we propose to apply the proposed requirements for section 1915(c) waiver programs to section 1915(i), (j), and (k) State plan services as appropriate.

Under section 1902(a)(19) of the Act, States must provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and that is in the best interest of Medicaid beneficiaries. While the needs of some individuals who receive HCBS may be relatively stable over some time periods, individuals who receive HCBS experience changes in their functional needs and individual circumstances, such as the availability of natural supports or a desire to choose a different provider, that necessitate revisions to the person-centered service plan to remain as independent as possible or to prevent adverse outcomes. The requirements to reassess functional need and to update the person-centered service plan based on the results of the reassessment, when circumstances or needs change significantly, or at the request of the individual are important safeguards that are in the best interest of beneficiaries because they ensure that an individual's section 1915(c) waiver program services change to meet the beneficiary's needs most appropriately as those needs change. Section 2402(a) of the Affordable Care Act (Pub. L. 111-148 and Pub. L. 111-152) requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are

responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to facilitate the participant's full engagement in community-life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁴⁶ In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS and to provide strategies for beneficiaries receiving such services to maximize their independence, while section 2402(a)(2) of the Affordable Care Act requires States to provide beneficiaries who need HCBS with the support and coordination needed to design a plan based on individual preferences and personal goals that support their full engagement in community life.

Effective State implementation of the person-centered planning process is integral to ensuring compliance with section 2402 of the Affordable Care Act. This is because this process is how States identify and document the service needs and choices of people receiving HCBS, plan for delivering individualized services that promote independence and self-direction, effectively coordinate services and supports necessary for community living, and ensure that the services and supports that people receive are responsive to their changing needs and choices. Each component of the person-centered planning process, including the functional assessment, developing and implementing the person-centered service plan, and periodically reassessing and updating of the service plan, are essential to ensuring States' compliance with sections 2402(a)(1) and (2) of the Affordable Care Act.

Since the release of the 2014 guidance, we have received feedback from States, the OIG, ACL, and OCR, and other interested parties on how crucial person-centered planning is in the delivery of care and the significance of the person-centered service plan for the assurance of

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⁴⁶ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.

health and welfare for section 1915(c) waiver program participants. The importance of the person-centered planning process to the assurance of health and welfare is supported by the existing regulatory requirements for section 1915(c) waivers, which indicate, at § 441.301(c)(2)(vi), that person-centered service plans must "reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies when needed" and, at § 441.301(c)(2)(xiii)(H), that person-centered service plans must "include an assurance that interventions and supports will cause no harm to the individual." As such, if States fail to conduct the required reassessment and updating of the person-centered service plan, they could increase the risk of harm for beneficiaries by not identifying risk factors and measures to minimize them and by not taking the steps necessary to assure that interventions and supports will not cause harm.

To ensure a more consistent application of person-centered service plan requirements across States and to protect the health and welfare of section 1915(c) waiver participants, we propose under our authority at sections 1915(c)(1) and 1902(a)(19) of the Act and section 2402(a)(1) and (2) of the Affordable Care Act, to codify a minimum performance level to demonstrate that States meet the requirements at § 441.301(c)(3). Specifically, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days.

We considered whether to propose to codify the minimum 86 percent performance level that was outlined in the 2014 guidance, instead of the minimum 90 percent performance level we are now proposing. The minimum 86 percent performance level was intended to provide States

with a reasonable threshold for demonstrating compliance with the requirements at § 441.301(c)(3). However, since we released the 2014 guidance, we have heard from many interested parties that a minimum 86 percent performance level may not be sufficient to demonstrate that a State is meeting these requirements. The key concern expressed is that this performance level provides States with more latitude than is necessary to account for unexpected delays in the timeframe for conducting reassessments and updating service plans, as States should assume that some delays are likely and account for them as part of their reassessment and service planning processes. Further, media and anecdotal reports indicate that re-assessment and care planning processes are often delayed without valid reasons, which suggests that beneficiaries may be at risk for preventable harm due to unnecessary delays in person-centered planning processes and that we should establish a more stringent threshold for States to demonstrate compliance with the requirements at § 441.301(c)(3). In response to the feedback we have received since 2014, we are proposing a slight increase to the minimum performance level outlined in the 2014 guidance. This proposed minimum performance level is intended to strengthen person-centered planning requirements based on feedback we have received, while also recognizing that there may be legitimate reasons why assessment and care planning processes occasionally are not completed timely in all instances.

We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we decided not to propose good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these minimum performance levels. Further, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster. We invite comment on these proposals.

At § 441.301(c)(3), we are also proposing to move the sentence beginning with "The person-centered service plan must be reviewed..." to a new paragraph at § 441.301(c)(3)(i) and to reposition the regulatory text under the proposed title, *Requirement*. In addition, we are proposing to revise the regulatory text at the renumbered paragraph, which currently says, "The person-centered service plan must be reviewed, and revised upon reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual" to read, "The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual." We are proposing this revision to the regulatory text so that it is clearer that the State is the required actor under § 441.301(c)(3). We are also proposing this revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the reassessment does not indicate a need for changes. With this proposed revision to the regulatory text, a State could, for instance, meet the requirement that the person-centered service plan was reviewed and revised as appropriate based on the results of the required reassessment of functional need by documenting that there were no changes in functional needs or the individual's circumstances upon reassessment that necessitated changes to the service plan.

Section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on an FFS basis or by a managed care entity to its enrollees. The requirement for "consistent administration" should require consistency between these two modes of service delivery. Accordingly, we are proposing to specify that a State must ensure compliance with the requirements in § 441.301(c)(3), with respect to HCBS delivered under both FFS and managed

care delivery systems. To ensure consistency in person-centered service plan requirements between FFS and managed care delivery systems, we propose to add the requirements at § 441.301(c)(3) to 42 CFR 438.208(c).

We also propose updates to existing language describing the person-centered planning process specific to section 1915(c) waivers. Current language describes the role of an individual's authorized representative as if every waiver participant will require an authorized representative, which is not the case and has been a source of confusion for States and providers. We propose to remove extraneous language from the regulation text at § 441.301(c)(1) to now read: "The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term 'individual' is used throughout this section, it includes the individual's authorized representative if applicable. In addition, the person-centered planning process: . . ." This proposed language brings the section 1915(c) waiver regulatory text in line with person-centered planning process language in both the section 1915(j) and (k) State plan options.

We recognize that many States may need time to implement these proposed requirements, including time to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.301(c)(3)(iii) to make the performance levels under § 441.301(c)(3)(ii) effective 3 years after the effective date of § 441.301(c)(3) (in other words, 3 years after the effective date of the final rule) in FFS delivery systems. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act that include HCBS in the managed care organization's (MCO), prepaid inpatient health plan's (PIHP), or prepaid ambulatory health plan's (PAHP) contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This

time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered this proposed timeframe based on all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe. As noted previously, the proposed requirements at § 441.301(c)(3), in combination with new proposed reporting requirements at § 441.311(b)(3) and other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting requirements and the required minimum 86 percent performance level for performance measures described in the 2014 guidance. We expect that States may implement some of the requirements proposed in this proposed rule in advance of the effective date. We will work with States to phase-out the requirements in the 2014 guidance as they implement the future requirements that become part of the final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

As discussed earlier in this section of the preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options have similar person-centered planning and service plan requirements, we are proposing to incorporate these new requirements within the applicable HCBS regulatory sections. Specifically, we propose to apply the proposed requirements at § 441.301(c)(3) to

section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements under section 1902(a)(19) of the Act, which authorizes safeguards necessary to assure that eligibility for care and services under the Medicaid program will be determined, and such care and services will be provided, in a manner consistent with the best interest of beneficiaries. We believe the same reasons for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities and are also responsive to feedback we have received from States and interested parties over the years requesting consistency of requirements across HCBS authorities. We request comment on the application of these provisions to section 1915(i), (j), and (k) authorities.

Finally, we considered whether to also apply these proposed requirements to section 1905(a) "medical assistance" State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services at this time, based on State feedback that States do not have the same data collection and reporting capabilities for these services as they do for other HCBS at section 1915(c), (i), (j), and (k), and because the person-centered planning and service plan requirements for section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Specifically, there are requirements for a "comprehensive assessment and periodic reassessment of individual needs" and "development (and periodic revision) of a specific care plan based on the information collected through the assessment" under § 440.169(d) for the provision of case management services. There are also requirements for a "plan of treatment" (or, at the option of the State, a "service plan") under § 440.167 for the provision of personal care services. However, §§ 440.169(d) and 440.167 do not include specific timeframes that could be used to establish minimum performance thresholds that would be similar to those proposed for section 1915(c) waivers. A face-to-face encounter within the 90 days before or within the 30 days after the start of the services is required at

§ 440.70(f)(1) for the initiation of home health services, and a written plan of care that the ordering practitioner reviews every 60 days for services is required under § 440.70(a)(2) for the provision of home health services. However, the proposed minimum thresholds for section 1915(c) waiver services would be incompatible with the required timeframes under § 440.70(a)(2) and (f)(1). Person-centered planning and service plan requirements are not required by Medicaid for other section 1905(a) services, although we recommend that States implement person-centered planning process for all HCBS. We note that the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. However, the small overall percentage includes large numbers of people with mental health needs who receive case management. We request comment on whether we should establish similar person-centered planning and service plan requirements for section 1905(a) State plan personal care, home health, and case management services.

2. Grievance System (§§ 441.301(c)(7), 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

As discussed earlier in section II.B.1., of this preamble, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁴⁷ Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. Further, section 1902(a)(19) of the Act requires States to provide safeguards to assure that

47 Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-

Pirection 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.

eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplicity of administration and the best interest of Medicaid beneficiaries.

Federal regulations at 42 CFR part 431, subpart E require States to provide Medicaid applicants and beneficiaries with an opportunity for a fair hearing before the State Medicaid agency in certain circumstances, including for a termination, suspension, or reduction of Medicaid eligibility, or for a termination, suspension, or reduction in benefits or services. These fair hearing rights apply to all Medicaid applicants and beneficiaries, including those receiving HCBS regardless of the delivery system. Under 42 CFR part 438, subpart F, Medicaid managed care plans must have in place: an appeal system that allows a Medicaid managed care enrollee to request an appeal, which is a review by the Medicaid managed care plan of an adverse benefit determination issued by the plan; and a grievance system, which allows a Medicaid managed care enrollee to file an expression of dissatisfaction with the plan about any matter other than an adverse benefit determination. Note that if a Medicaid managed care enrollee exhausts the Medicaid managed care plan's appeals process, the enrollee may request a fair hearing before the State Medicaid agency. Medicaid managed care enrollees cannot request a fair hearing for grievances because grievances are not generally related to the direct provision of services. Section 1902(a)(3) of the Act provides for the opportunity for a State fair hearing when a "claim" for medical assistance under the plan is denied or is not acted upon with reasonable promptness." This structure creates a disparity for FFS HCBS beneficiaries, as it does not provide for a venue to raise concerns about issues that HCBS beneficiaries may experience which are not subject to the fair hearing process, such as the failure of a provider to comply with the HCBS settings requirements at § 441.301(c)(4) (note that these are issues for which a managed care enrollee could file a grievance with their plan).

Under our authority at section 1902(a)(19) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we propose to require at new § 441.301(c)(7) that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program

services through an FFS delivery system. Specifically, we propose at § 441.301(c)(7) that States must establish a procedure under which a beneficiary can file a grievance related to the State's or a provider's compliance with the person-centered planning and service plan requirements at §§ 441.301(c)(1) through (3) and the HCBS settings requirements at §§ 441.301(c)(4) through (6). This proposal is based on feedback obtained during various public engagement activities conducted with interested parties over the past several years about the need for beneficiary grievance processes in section 1915(c) waiver programs related to these requirements. However, to avoid duplication with the grievance requirements at part 438, subpart F, we are not proposing to apply this requirement to establish a grievance procedure to managed care delivery systems. We note, though, that the proposals in this section are similar to requirements for managed care grievance requirements found at part 438, subpart F, with any differences reflecting changes appropriate for FFS systems. The proposed requirements included at § 441.301(c)(7) in this proposed rule are focused specifically on grievance systems and do not establish new fair hearing system requirements, as appeals of adverse eligibility and/or benefit or service determinations are addressed by existing fair hearing requirements at 42 CFR part 431, subpart E. We welcome comments on any additional changes we should consider in this section.

As discussed earlier in this section of the preamble, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and monitoring of an HCBS complaint system. In addition, section 2402(a)(3)(A) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid HCBS, develop HCBS systems that achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. As such, we believe the requirement for States to establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system are necessary to comply with the HCBS complaint system requirements at section 2402(a)(3)(B)(ii) and to ensure consistency in the administration of HCBS between managed care and FFS delivery systems.

Further, in the absence of a grievance system requirement for FFS HCBS programs, States may not have established processes and systems for people receiving section 1915(c) waiver program services through FFS delivery systems to express dissatisfaction with or voice concerns related to States' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), as such concerns are not subject to the existing fair hearing process at 42 CFR part 431 subpart E. As a result, we believe the proposal for a grievance system for FFS HCBS programs is necessary to assure that care and services will be provided in a manner that is in the best interests of the beneficiaries, as required by section 1902(a)(19) of the Act.

We have specifically focused this requirement on States' and providers' compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) because of the critical role that person-centered planning and the service plan play in appropriate care delivery for people receiving HCBS. Additionally, we have focused the grievance system requirements on the HCBS settings requirements because of the importance of the HCBS settings requirements to ensuring that HCBS beneficiaries have full access to the benefits of community living and are able to receive services in the most integrated setting appropriate to their needs. Beneficiary advocates and other interested parties have also indicated to us that these are especially important areas for which to ensure that grievance processes are in place for all Medicaid beneficiaries receiving HCBS. Further, focusing the grievance systems requirements on the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6) helps to ensure that the proposed grievance requirements do not duplicate or conflict with existing fair hearing requirements at part 431, subpart E, as HCBS settings requirements and person-centered planning requirements are outside the scope of the fair hearing requirements.

At § 441.301(c)(7)(ii)(A), we propose to define "grievance" as an expression of dissatisfaction or complaint related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6), regardless of whether the beneficiary requests that remedial action be taken to address the area of dissatisfaction or complaint. At § 441.301(a)(7)(ii)(B), we also propose to define "grievance system" as the processes the State implements to handle grievances, as well as the processes to collect and track information about them. To ensure consistency in the administration of HCBS between managed care and FFS delivery systems, we based these definitions on the definitions at part 438, subpart F.

At § 441.301(c)(7)(iii)(A) through (C), we propose new general requirements for States' grievance procedures. Specifically, at § 441.301(c)(7)(iii)(A), we propose to require that a beneficiary or authorized representative be permitted to file a grievance. Under the proposal, another individual or entity may file a grievance on a beneficiary's behalf, so long as the beneficiary or authorized representative provides written consent. Our proposal would not permit a provider to file a grievance that would violate conflict of interest guidelines, which States are required to have in place under § 441.540(a)(5). At § 441.301(c)(7)(iii)(A), we also propose to specify that all references to beneficiary in the regulatory text of this section includes the beneficiary's representative, if applicable.

At § 441.301(c)(7)(iii)(B)(1) through (7), we propose to require States to:

- Have written policies and procedures for their grievance processes that at a minimum meet the requirements of this proposed section and serve as the basis for the State's grievance process;
- Provide beneficiaries with reasonable assistance in completing the forms and procedural steps related to grievances and to ensure that the grievance system is consistent with the availability and accessibility requirements at § 435.905(b);

- Ensure that punitive action is not threatened or taken against an individual filing a grievance;
- Accept grievances, requests for expedited resolution of grievances, and requests for extensions of timeframes from beneficiaries;
- Provide beneficiaries with notices and other information related to the grievance system, including information on their rights under the grievance system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);
 - Review grievance resolutions with which beneficiaries are dissatisfied; and
- Provide information on the grievance system to providers and subcontractors approved to deliver services under section 1915(c) of the Act.

At § 441.301(c)(7)(iii)(C)(1) through (5), we propose to require that the processes for handling grievances must:

- Allow beneficiaries to file a grievance either orally or in writing;
- Acknowledge receipt of each grievance;
- Ensure that decisions on grievances are not made by anyone previously involved in review or decision-making related to the problem or issue for which the beneficiary has filed a grievance or a subordinate of such an individual, are made by individuals with appropriate expertise, and are made by individuals who consider all of the information submitted by the beneficiary related to the grievance;
- Provide beneficiaries with a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance;
- Provide beneficiaries, free of charge and in advance of resolution timeframes, with their own case files and any new or additional evidence used or generated by the State related to the grievance; and

• Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with 435.905(b), to support their participation in grievance processes and their use of the grievance system.

At § 441.301(c)(7)(iv)(A), we propose to require that the beneficiary be able to file a grievance at any time. At § 441.301(c)(7)(iv)(B), we propose to require that beneficiaries be permitted to request expedited resolution of a grievance, whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, such as if, for example, a beneficiary cannot access personal care services authorized in the person-centered service plan.

At § 441.301(c)(7)(v), we propose resolution and notification requirements for grievances. Specifically, at § 441.301(c)(7)(v)(A), we propose to require that States resolve and provide notice of resolution related to each grievance as quickly as the beneficiary's health, safety, and welfare requires and within State-established timeframes that do not exceed the standard and expedited timeframes proposed in § 441.301(c)(7)(v)(B). At § 441.301(c)(7)(v)(B)(1), we propose to require that standard resolution of a grievance and notice to affected parties must occur within 90 calendar days of receipt of the grievance. At § 441.301(c)(7)(v)(B)(2), we propose to require that expedited resolution of a grievance and notice must occur within 14 calendar days of receipt of the grievance.

At § 441.301(c)(7)(v)(C), we propose that States be permitted to extend the timeframes for the standard resolution and expedited resolution of grievances by up to 14 calendar days if the beneficiary requests the extension, or the State documents that there is need for additional information and how the delay is in the beneficiary's interest. At § 441.301(c)(7)(v)(D), we propose to require that States make reasonable efforts to give the beneficiary prompt oral notice of the delay, give the beneficiary written notice, within 2 calendar days of determining a need for a delay but no later than the timeframes in paragraph (c)(7)(v)(B), of the reason for the decision to extend the timeframe, and resolve the grievance as expeditiously as the beneficiary's health

condition requires and no later than the date the extension expires, if the State extends the timeframe for a standard resolution or an expedited resolution.

We note that the proposed requirements at § 441.301(c)(7)(iv)(B) that beneficiaries be permitted to request expedited resolution of a grievance and at § 441.301(c)(7)(v)(B)(2) related to the timeframe for expedited resolution of a grievance and notice differ from the current grievance system requirements for Medicaid managed care plans at part 438, subpart F, which do not include specific requirements for an expedited resolution of a grievance. We invite comment on whether part 438, subpart F should be amended to include the proposed requirements at § 441.301(c)(7)(iv)(B) and at § 441.301(c)(7)(v)(B)(2).

Proposed § 441.301(c)(7)(vi) describes proposed requirements related to the notice of resolution for beneficiaries. Specifically, at § 441.301(c)(7)(vi)(A), we propose to require that States establish a method for written notice to beneficiaries and that the method meet the availability and accessibility requirements at § 435.905(b). At § 441.301(c)(7)(vi)(B), we propose to require that States make reasonable efforts to provide oral notice of resolution for expedited resolutions.

Proposed § 441.301(c)(7)(vii) lists proposed recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we propose to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(1) through (6), we propose to require that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we propose to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We recognize that many States may need time to implement these requirements, including to amend provider agreements, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. However, we also recognize that the absence of a grievance system in FFS HCBS systems poses a substantial risk of harm to beneficiaries. As a result, we are proposing at § 441.301(c)(7)(viii) that the requirement at § 441.301(c)(7) be effective 2 years after the effective date of the final rule. A 2-year time period after the effective date of the final rule for States to implement these requirements reflects our attempt to balance two competing challenges: (1) the fact that there is a gap in existing regulations for FFS HCBS grievance processes related to important HCBS beneficiary protection issues involving person-centered planning and HCBS settings requirements; and (2) feedback from States and other interested parties that it could take 1 to 2 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on overall burden for States to meet the requirements of this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (1 year to 18 months) or longer timeframe (3 to 4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because HCBS State plan options also must comply with the HCBS Settings Rule and with similar

person-centered planning and service plan requirements, we are proposing to incorporate these grievance requirements within the applicable regulatory sections. Specifically, we propose to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively.

Consistent with our proposal for section 1915(c) waivers, we propose to apply the proposed grievance requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries and our authority at section 2402(a)(3)(B)(ii) of the Affordable Care Act to require a complaint system for beneficiaries. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable to these other HCBS authorities. We request comment on the application of the grievance system provisions to section 1915(i), (j), and (k) authorities. We note that in the language added to § 441.464(d)(2)(v), we identify that the proposed grievance requirements apply when self-directed personal assistance services authorized under section 1915(j) include services under a section 1915(c) waiver program. As described later in this section of this proposed rule, we have not proposed to apply these requirements to section 1905(a) services; section 1905(a) personal care services are the other service authorized under section 1915(j) authorities to be self-directed.

We considered whether to also apply the proposed requirements to section 1905(a) "medical assistance" State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services because section 1905(a) services are not required to comply with HCBS settings requirements and because the person-centered planning and service plan requirements for most section 1905(a) services are substantially different from those for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k)

authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should establish grievance requirements for section 1905(a) State plan personal care, home health, and case management services.

3. Incident management system (§§ 441.302(a)(6), 441.464(e), 441.570(e), and 441.745(a)(1)(v))

Section 1902(a)(19) of the Act requires States to provide safeguards as may be necessary to assure that eligibility for care and services will be determined, and that "such care and services will be provided," in a manner consistent with simplicity of administration and "the best interests of the recipients." Section 1915(c)(2)(A) of the Act and current Federal regulations at § 441.302(a) require that States have in place necessary safeguards to protect the health and welfare of individuals receiving section 1915(c) waiver program services. Further, as discussed previously in section II.B.1. of this preamble, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide support and coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁴⁸ Among other things, section 2402(a)(3)(B)(ii) of the Affordable Care Act requires development and oversight of a system to qualify and monitor providers.

As noted earlier in section II.B.1. of this preamble we released guidance for section 1915(c) waiver programs in 2014 which noted that States should report on State-developed performance measures to demonstrate that they meet six assurances, including a Health and Welfare assurance for States to demonstrate that they have designed and implemented an

⁴⁸ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.

effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance highlighted, related to the Health and Welfare assurance, the following:

- The State demonstrates on an ongoing basis that it identifies, addresses, and seeks to prevent instances of abuse, neglect, exploitation, and unexplained death;
- The State demonstrates that an incident management system is in place that effectively resolves incidents and prevents further similar incidents to the extent possible;
- The State policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed;
- The State establishes overall health care standards and monitors those standards based on the responsibility of the service provider as stated in the approved waiver.

Consistent with the expectations for other performance measures, the 2014 guidance noted that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their Health and Welfare performance measures.

Despite States implementing these statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and States' adherence to related subregulatory guidance, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid. For example, a 2018 report, "Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight," (referred to as the Joint Report, developed by ACL, OCR, and the OIG), found systemic problems with health and safety policies and procedures being followed in group homes and that failure to comply with these policies and procedures left beneficiaries in group homes at risk of serious harm.

⁴⁹ Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight. US Department of Human Services, Office of the Inspector General, Administration for Community Living, and Office for Civil Rights. January 2018. Accessed at https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes-joint-report.pdf.

In addition, in 2016 and 2017, OIG released several reports on their review of States' compliance with Federal and State requirements regarding critical incident reporting and monitoring. ^{50,51,52} OIG found that several States did not comply with Federal waiver and State requirements for reporting and monitoring critical incidents involving individuals receiving HCBS through waivers. In particular, they reported that:

- Critical incidents were not reported correctly;
- Adequate training to identify appropriate action steps for reported critical incidents or reports of abuse or neglect was not provided to State staff;
- Appropriate data sets to trend and track critical incidents were not accessible to State staff; and
- Critical incidents were not clearly defined, making it difficult to identify potential abuse or neglect.

In 2016, we conducted three State audits based at least in part on concerns regarding health and welfare and media coverage on abuse, neglect, or exploitation issues.⁵³ We found that these three States had not been meeting their section 1915(c) waiver assurances, similar to findings reported by the OIG. In two cases, for the incidents of concern, tracking and trending of critical incidents were not present. Further, in at least two of the States, staffing at appropriate levels was identified as an issue.

In January 2018, the United States Government Accountability Office (GAO) released a report on a study of 48 States that covered assisted living services.⁵⁴ The GAO found large inconsistencies between States in their definition of a critical incident and their system's ability

⁵⁰ HHS OIG. "Connecticut did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries." May 2016. Accessed at https://oig.hhs.gov/oas/reports/region1/11400002.pdf.

⁵¹ HHS OIG. "Massachusetts did not comply with Federal and State requirements for critical incidents involving developmentally disabled Medicaid beneficiaries." July 2016. Accessed at https://oig.hhs.gov/oas/reports/region1/11400008.pdf.

⁵² HHS OIG. "Maine did not comply with Federal and State requirements for critical incidents involving Medicaid beneficiaries with developmental disabilities." August 2017. Accessed at https://oig.hhs.gov/oas/reports/region1/11600001.pdf.

⁵³ Presentation by CMS for Advancing States: Quality in the HCBS Waiver – Health and Welfare. See: http://www.nasuad.org/sites/nasuad/files/Final%20Quality%20201.pdf.

⁵⁴ Government Accountability Office. "Medicaid assisted living services – improved Federal oversight of beneficiary health and welfare is needed." January 2018. Accessed at https://www.gao.gov/assets/690/689302.pdf.

to report, track, and collect information on critical incidents that have occurred. States also varied in their oversight methods as well as the type of information they were reviewing as part of this oversight. The GAO recommended that requiring States to report information on incidents (such as the type and severity of incidents and the number of incidents) would strengthen the effectiveness of State and Federal oversight.

In July 2019, we issued a survey to States that operate section 1915(c) waivers, requesting information on their approach to administering incident management systems. The goal of the survey was to obtain a comprehensive understanding of how States organize their incident management system to best respond to, resolve, monitor, and prevent critical incidents in their waiver programs. The survey found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and
- Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Additionally, during various public engagement activities conducted with interested parties over the past several years, we have heard that ensuring access to HCBS requires that we must first ensure health and safety systems are in place across all States, a theme underscored by the Joint Report.

Based on these findings and reports, under the authorities at sections 1902(a)(19) and 1915(c)(2)(A) of the Act and section 2402(a)(3)(B)(ii) of the Affordable Care Act, we propose a

new requirement at § 441.302(a)(6) to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. This proposal is intended to ensure standardized requirements for States regarding incidents that harm or place a beneficiary at risk of harm and is based on our experience working with States as part of the section 1915(c) waiver program and informed by the incident management survey described previously in this section of the proposed rule. In the absence of an incident management system, people receiving section 1915(c) waiver program services are at risk of preventable or intentional harm. As such, we believe that such a system to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services.

At § 441.302(a)(6)(i)(A) through (G), we propose new requirements for States' incident management systems. Specifically, at § 441.302(a)(6)(i)(A), we propose to establish a minimum standard definition of a critical incident to include, at a minimum, verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect. Currently, there is no standardized Federal definition for the type of events or instances that States should consider a critical incident that must be reported by a provider to the State and considered for an investigation by the State to assess whether the incident was the result of abuse, neglect, or exploitation, and whether it could have been prevented. The proposed definition at § 441.302(a)(6)(i)(A) is based on internal analyses of data and information obtained through a CMS survey of States' incident management systems, commonalities across definitions, and common gaps in States' definitions of critical incidents (for instance, that many States do not

consider sexual assault to be a critical incident). We request comment on whether there are specific types of events or instances of serious harm to section 1915(c) waiver participants, such as identity theft or fraud, that would not be captured by the proposed definition and that should be included, and whether the inclusion of any specific types of events or instances of harm in the proposed definition would lead to the overidentification of critical incidents.

At § 441.302(a)(6)(i)(B), we propose to require that States have electronic critical incident systems that, at a minimum, enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. We request comment on the burden associated with requiring States to have electronic critical incident systems and whether there is specific functionality, such as unique identifiers, that should be required or encouraged for such systems. Although we are not proposing to require States to do so, States are also encouraged to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR, part 170 and other relevant standards identified in the Interoperability Standards Advisory (ISA).⁵⁵ We also remind States that enhanced FFP is available at a 90 percent FMAP for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements.⁵⁶ Enhanced FFP at a 75 percent FMAP is also available for operations of such systems, in accordance with applicable Federal requirements.⁵⁷ However, we note that receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective.⁵⁸

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⁵⁵ Relevant standards adopted by HHS and identified in the ISA include the USCDI (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi), eLTSS (https://www.healthit.gov/isa/documenting-care-plans-person-centered-services), and Functional Assessment Standardized Items (https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability).
⁵⁶ See section 1903(a)(3)(A)(i) and § 433.15(b)(3), 80 FR 75817-75843; https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.

⁵⁷ See section 1903(a)(3)(B) and § 433.15(b)(4).

⁵⁸ See § 433.112 (b, 80 FR 75841; https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.

At § 441.302(a)(6)(i)(C), we propose to require States to require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or any critical incidents that are a result of the failure to deliver authorized services. Based on the findings of the Joint Report, as well as the OIG and GAO reports cited earlier, settings in which residential habilitation and day habilitation services are provided, and services provided in a beneficiary's private home by a provider should be of particular focus. We believe that such a requirement will help to specify provider expectations for reporting critical incidents and to ensure that harm that occurs because of the failure to deliver services will be appropriately identified as a critical incident.

At § 441.302(a)(6)(i)(D), we propose to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. We believe that such data can play an important role in identifying serious instances of harm to waiver program participants, which may be unreported by a provider, such as a death that occurs as a result of choking of an individual with a developmental disability residing in a group home, or a burn that occurs because a provider failed to appropriately supervise someone with dementia and that results in an emergency department visit. We request comment on whether States should be required to use these data sources to identify unreported critical instances, and whether there are other specific data sources that States should be required to use to identify unreported critical incidents.

At § 441.302(a)(6)(i)(E), we propose to require that States share information, consistent with the regulations in 42 CFR part 431, subpart F, on the status and resolution of investigations. We expect this data sharing could be accomplished through the use of information sharing

agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation. We also propose, at § 441.302(a)(6)(i)(F), to require States to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. These proposed requirements are intended to ensure that the failure to effectively share information between State agencies or other entities in the State responsible for investigating incidents does not impede a State's ability to effectively identify, report, triage, investigate, resolve, track, and trend critical incidents, particularly where there could be evidence of serious harm or a pattern of harm to a section 1915(c) waiver program participant for which a provider is responsible.

As noted in section II.B.1. of this proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we indicated that States should report on State-developed performance measures across several domains, including to demonstrate that the State designed and implemented an effective system for assuring waiver participant health and welfare. Specifically, the 2014 guidance noted that States should demonstrate: on an ongoing basis that they identify, address, and seek to prevent instances of abuse, neglect, exploitation, and unexplained death; that an incident management system is in place that effectively resolves those incidents and prevents further similar incidents to the extent possible; State policies and procedures for the use or prohibition of restrictive interventions (including restraints and seclusion) are followed; and overall health care standards are established and monitored. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure

the correctness and verification of such reports. Under our authority at section 1902(a)(6) of the Act, we propose to modernize the health and welfare reporting by requiring all States to report on the same Federally prescribed quality measures as opposed to the State-developed measures, which naturally vary State by State. Specifically, at new § 441.302(a)(6)(i)(G), we propose to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We discuss these reporting requirements in our discussion of proposed § 441.311(b)(1). Further, under our authority at sections 1915(c)(2)(A) and 1902(a)(19) of the Act, we propose to codify a minimum performance level to demonstrate that States meet the requirements at § 441.302(a)(6). Specifically, at new § 441.302(a)(6)(ii)(A) through (C), we propose to require that States demonstrate that an investigation was initiated, within State-specified timeframes, for no less than 90 percent of critical incidents; an investigation was completed and the resolution of the investigation was determined, within State-specified timeframes, for no less than 90 percent of critical incidents; and corrective action was completed, within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.

While we expect States to meet State-specified timeframes for initiating investigations, completing investigations and determining resolution, and completing corrective action plans for all critical incidents, we are proposing to establish a minimum 90 percent performance level in each of these areas in recognition of the various scenarios that may impact a State's ability to meet these timeframes for each critical incident (for example, some critical incidents may require more complex investigations than others, an illness may delay the interview of an important witness to the incident).

We considered whether to codify the minimum 86 percent performance level that was established in the 2014 guidance, instead of the minimum 90 percent performance level we have proposed. The minimum 86 percent performance level was intended to provide States with a reasonable threshold for demonstrating compliance with the requirements at § 441.302(a)(6).

However, we have conducted extensive oversight and received significant feedback from external parties since we released the 2014 guidance. Our findings from the oversight and feedback have led us to conclude that the minimum 86 percent performance level may not be sufficient to demonstrate a State is meeting these requirements because it provides States with more latitude than is necessary to account for unexpected delays in the timeframes for investigating and addressing critical incidents. Further, findings from our 2016 audits and 2019 survey, feedback from States, OIG, ACL, OCR, and other interested parties, and media and anecdotal reports document the harm that beneficiaries can experience when States fail to investigate and address critical incidents and indicate that we should establish a more stringent threshold for States to demonstrate compliance with the requirements at § 441.302(a)(6). As a result, we are proposing an increase to the minimum performance level in the 2014 guidance. This proposed minimum performance level is intended to strengthen health and welfare reporting requirements based on feedback and evidence we have received, while also recognizing that there may be legitimate reasons for delays in investigating and addressing critical incidents.

We also considered whether to propose allowing good cause exceptions to the minimum performance level in the event of a natural disaster, public health emergency, or other event that would negatively impact a State's ability to achieve a minimum 90 percent performance level. In the end, we are not proposing good cause exceptions because the minimum 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Further, as noted earlier with the person-centered service plan requirements in section II.B.1. of this preamble, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

At § 441.302(a)(6)(iii), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve

coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for "consistent administration" should require consistency between these two modes of service delivery. We accordingly are proposing to identify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As noted throughout the HCBS proposals in this rule, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.302(a)(6)(iii) to provide States with 3 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered all of the HCBS proposals outlined in proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

Again, the proposed requirements at §§ 441.302(a)(6)(iii) and 441.311(b)(1), in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance. We expect that States may implement some of the requirements proposed in this proposed rule in advance of the effective date. To reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements, we will work with States to phase-out the 2014 guidance as they implement these proposed requirements should a final rule be adopted.

Additionally, as discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs and because of the importance of assuring health and welfare for other HCBS State plan options, we are proposing to incorporate these incident management requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements § 441.302(a)(6) to section 1915(i), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(19) of the Act to assure that there are safeguards for beneficiaries. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.464(e) and (f) (discussed later in section II.B.5. of this proposed rule), we are

proposing to renumber existing \S 441.464(e) as \S 441.464(g) and existing \S 441.464(f) as \S 441.464(h).

Finally, we considered whether to also apply the proposed incident management system and critical incident reporting and performance threshold requirements to section 1905(a) "medical assistance" State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should establish similar health and welfare requirements for section 1905(a) State plan personal care, home health, and case management services.

4. Reporting (§ 441.302(h))

Proposed § 441.311, described in section II.B.7. of this proposed rule, establishes a new *Reporting Requirements* section. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires HHS to promulgate regulations to ensure that States develop HCBS systems that are designed to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In addition to supporting States with achieving a more consistent administration of policies and procedures across HCBS programs in accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act, we believe that standardizing reporting across HCBS authorities will streamline and simplify reporting for providers, improve States' and CMS's ability to assess HCBS quality and performance, and better enable States to improve the quality of HCBS programs through the availability of comparative data. Further, section 1902(a)(6) of the Act

requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports.

To avoid duplicative or conflicting reporting requirements at § 441.302(h), we propose to amend § 441.302(h) by removing the following language: "annually"; "The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on -"; and by removing paragraphs (1) and (2) under § 441.302(h). Further, we propose to add ", including the data and information as required in § 441.311" at the end of the new amended text, "Assurance that the agency will provide CMS with information on the waiver's impact." By making these changes, we are consolidating reporting expectations in one new section at proposed § 441.311, described in section II.B.7. of this proposed rule, under our authority at section 1902(a)(6) of the Act and section 2402(a)(3)(A) of the Affordable Care Act. As noted earlier in section II.B.1. of this proposed rule, this reporting will supersede existing reporting for section 1915(c) waivers and standardize reporting across section 1915 HCBS authorities.

5. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))

Section 1902(a)(30)(A) of the Act requires State Medicaid programs to ensure that payments to providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. Access to most HCBS generally requires hands-on and in-person services to be delivered by direct care workers. Direct care workers are referred to by various names, such as direct support professionals, personal care attendants, and home health aides, within and across States. They perform a variety of roles, including nursing services, assistance with activities of daily living (such as mobility, personal hygiene, eating) and instrumental activities of daily living (such as cooking, grocery shopping, managing finances), behavioral supports, employment supports, and other services to

promote community integration for older adults and people with disabilities. We discuss the definition of direct care workers in more detail below in the context of our proposed definition of direct care workers.

Direct care workers typically earn low wages and receive limited benefits, ^{59,60,61} contributing to a shortage of direct care workers and high rates of turnover in this workforce, which can limit access to and impact the quality of HCBS. Workforce shortages can also reduce the cost-effectiveness of services for State Medicaid agencies that take into account the actual cost of delivering services when determining Medicaid payment rates, such as by increasing the reliance on overtime and temporary staff, which have higher hourly costs than non-overtime wages paid to permanent staff. Further, an insufficient supply of HCBS providers can prevent individuals from transitioning from institutions to home and community-based settings and from receiving HCBS that can prevent institutionalization. HCBS is, on average, less costly than institutional services, ^{62,63} and most older adults and people with disabilities strongly prefer to live in the community. Accordingly, limits on the availability of HCBS lessen the ability for State Medicaid programs to deliver LTSS in a cost-effective, beneficiary friendly manner.

Shortages of direct care workers and high rates of turnover also reduce the quality of HCBS. For instance, workforce shortages can prevent individuals from receiving needed services and, in turn, lead to poorer outcomes for people who need HCBS. Insufficient staffing can also make it difficult for providers to achieve quality standards.⁶⁴ High rates of turnover can

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⁵⁹ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.

⁶⁰ Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf. We recognize that there are workforce shortages that may impact access to other Medicaid-covered services aside from HCBS. We are focusing in this proposed rule on addressing workforce shortages in HCBS and continue to assess the feasibility and potential impact of other actions to address workforce shortages in other parts of the health care sector.

⁶² Reaves, E.L., & Musumeci, M.B. December 15, 2015. *Medicaid and Long-Term Services and Supports: A Primer*. Kaiser Family Foundation. Accessed at https://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/. 63 Kim, M-Y, Weizenegger, E., & Wysocki, A. July 22, 2022. *Medicaid Beneficiaries Who Use Long-Term Services and Supports: 2019*. Chicago, IL: Mathematica. Accessed at https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.

⁶⁴ American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at

reduce quality of care,⁶⁵ including through the loss of experienced and qualified workers and by reducing continuity of care people receiving HCBS,⁶⁶ which is associated with the reduced likelihood of improvement in function among people receiving home health aide services.⁶⁷

While workforce shortages have existed for years, the COVID-19 pandemic has exacerbated the problem, leading to higher rates of direct care worker turnover (for instance, due to higher rates of worker-reported stress), an inability of some direct care workers to return to their positions prior to the pandemic (for instance, due to difficulty accessing child care or concerns about contracting COVID-19 for people with higher risk of severe illness), workforce shortages across the health care sector, and wage increases in retail and other jobs that tend to draw from the same pool of workers as some HCBS. 68,69,70 Further, demand for direct care workers is expected to continue rising due to the growing needs of the aging population, the changing ability of aging caregivers to provide supports, a broader societal shift away from institutional services and towards services that are integrated in the community, and a decline in the number of younger workers available to provide services. ^{71,72,73} As discussed previously in section II.B.1. of this proposed rule, section 2402(a) of the Affordable Care Act requires the Secretary of HHS to ensure that all States receiving Federal funds for HCBS, including Medicaid, develop HCBS systems that are responsive to the needs and choices of beneficiaries receiving HCBS, maximize independence and self-direction, provide coordination for and

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⁶⁵ Newcomer R , Kang T , Faucett J . Consumer-directed personal care: comparing aged and non-aged adult recipient health-related outcomes among those with paid family versus non-relative providers. Home Health Care Serv Q. 2011;30(4):178–97.
66 Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.
67 Russell D , Rosati RJ , Peng TR , Barrón Y , Andreopoulos E . Continuity in the provider of home health aide services and the likelihood of patient improvement in activities of daily living. Home Health Care Manage Pract. 2013;25(1):6–12.
68 MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.
69 Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.
70 American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at

https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

71 MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March

^{2022.} Accessed at https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.

72 Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.

73 Centers for Medicare and Medicaid Services. November 2020. Long-Term Services and Supports Rebalancing Toolkit. Accessed at https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-toolkit.pdf.

support each person's full engagement in community life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS.⁷⁴ In particular, section 2402(a)(1) of the Affordable Care Act requires States to allocate resources for services in a manner that is responsive to the changing needs and choices of beneficiaries receiving HCBS, while section 2402(a)(3)(B)(iii) of the Affordable Care Act requires States to oversee and monitor HCBS system functions to assure a sufficient number of qualified direct care workers to provide self-directed personal assistance services. To comply with sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, States must have a sufficient direct care workforce to be able to deliver services that are responsive to the changing needs and choices of beneficiaries, and, specifically, a sufficient number of qualified direct care workers to provide self-directed personal assistance services.

Consistent with section 1902(a)(30)(A) of the Act and sections 2402(a)(1) and 2402(a)(3)(B)(iii) of the Affordable Care Act, we propose to require that State Medicaid agencies demonstrate that payment rates for certain HCBS authorized under section 1915(c) of the Act are sufficient to ensure a sufficient direct care workforce (defined and explained later in this section of the proposed rule) to meet the needs of beneficiaries and provide access to services in accordance with the amount, duration, and scope specified in the person-centered service plan, as required under § 441.301(c)(2). We believe that this proposal supports the economy, efficiency, and quality of HCBS authorized under section 1915(c) of the Act, by ensuring that a sufficient portion of State FFS and managed care payments for HCBS go directly to compensation of the direct care workforce. While many States have already voluntarily established such minimums for payments authorized under section 1915(c) of the Act, ⁷⁵ we

⁷⁴ Section 2402(a) of the Affordable Care Act – Guidance for Implementing Standards for Person-Centered Planning and Self-Direction in Home and Community-Based Services Programs. Accessed at https://acl.gov/sites/default/files/news%202016-10/2402-a-Guidance.pdf.

⁷⁵ For instance, as part of their required activities to enhance, expand, or strengthen HCBS under ARP section 9817, some States have required that a minimum percentage of rate increases and supplemental payments go to the direct care workforce. See https://www.medicaid.gov/medicaid/home-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html for more information on ARP section 9817.

believe a Federal standard would support ongoing access to, and quality and efficiency of, HCBS.

This proposal is designed to affect the inextricable link between sufficient payments being received by the direct care workforce and access to and, ultimately, the quality of HCBS received by Medicaid beneficiaries. We believe that this proposal would not only benefit direct care workers but also individuals receiving Medicaid HCBS because supporting and stabilizing the direct care workforce will result in better qualified employees, lower turnover, and a higher quality of care. The direct care workforce must be able to attract and retain qualified workers in order for beneficiaries to access providers of the services they have been assessed to need and for the direct care workforce to be comprised of workers with the training, expertise, and experience to meet the diverse and often complex HCBS needs of individuals with disabilities and older adults. Without access to a sufficient pool of direct care providers, individuals are forced to forgo having their needs met or addressed by workers without sufficient training, expertise, or experience to meet their unique needs, both of which could lead to worsening health and quality of life outcomes, loss of independence, and institutionalization.^{76,77,78,79} Further, we believe that ensuring adherence to a Federal standard of the percentage of Medicaid payments going to direct care workers is a concrete step in recruitment and retention efforts to stabilize this workforce by enhancing salary competitiveness in the labor market. In the absence of such requirements, we are unable to support and stabilize the direct care workforce because we are unable to ensure that the payments are used primarily and substantially to pay for care and services provided by direct care workers. Therefore, at § 441.302(k)(3)(i), we propose to require that at least 80 percent of

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⁷⁶ MACPAC Issue Brief. State Efforts to Address Medicaid Home- and Community-Based Services Workforce Shortages. March 2022. Accessed at https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.

Campbell, S., A. Del Rio Drake, R. Espinoza, K. Scales. 2021. Caring for the future: The power and potential of America's direct care workforce. Bronx, NY: PHI http://phinational.org/wp-content/uploads/2021/01/Caring-for-the-Future-2021-PHI.pdf.
 American Network of Community Options and Resources (ANCOR). 2021. The state of America's direct support workforce 2021. Alexandria, VA: ANCOR. Accessed at

https://www.ancor.org/sites/default/files/the_state_of_americas_direct_support_workforce_crisis_2021.pdf.

⁷⁹ Chong, N., I. Akorbirshoev, J. Caldwell, H.S. Kaye, and M. Mitra. 2021. The relationship between unmet need for home and community-based services and health and community living outcomes. Disability Health Journal. Accessed at https://www.sciencedirect.com/science/article/abs/pii/S1936657421001953.

all Medicaid payments, including but not limited to base payments and supplemental payments, with respect to the following services be spent on compensation to direct care workers: homemaker services, home health aide services, and personal care services.⁸⁰

This proposal is based on feedback from States that have implemented similar requirements for payments for certain HCBS under section 9817 of the ARP81 or other State-led initiatives. These States have reported to us through various public engagement activities that similar requirements have had their intended effect of ensuring that a sufficient portion of the payment for Medicaid HCBS goes to compensation for the direct care workforce. These States have also indicated an 80 percent threshold is an appropriate threshold that takes into account the expected portion of payments that are necessary for provider administrative and other costs, aside from direct care worker compensation, although our research indicates that some States have successfully implemented other thresholds, ranging from a low of around 75 percent⁸² to a high of 90 percent. We have also focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers. These are services that would most commonly be conducted in individuals' homes and general community settings. As such, there should be low facility or other indirect costs associated with the services. We request comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for homemaker services, home health aide services, and personal care services: (1) 75 percent; (2) 85 percent; and (3)

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⁸⁰ We note that section 2402(a) of the Affordable Care Act applies broadly to all HCBS programs and services funded by HHS. Further, section 2402(a) does not include limits on the scope of services, HCBS authorities, or other factors related to its use of the term HCBS. Therefore, we believe that there is no indication that personal care, homemaker, and home health aide services would fall outside the scope of section 2402(a).

⁸¹ Information on State activities to expand, enhance, or strengthen HCBS under ARP section 9817 can be found on Medicaid.gov at https://www.medicaid.gov/medicaid/home-community-based-services/guidance/strengthening-and-investing-home-and-community-based-services-for-medicaid-beneficiaries-american-rescue-plan-act-of-2021-section-9817/index.html.
82 Minnesota has established a minimum threshold of 72.5 percent, while Illinois has implemented a minimum threshold of 77 percent, for similar requirements for HCBS as we are proposing. See https://www.revisor.mn.gov/statutes/cite/256B.85/pdf and https://casetext.com/regulation/illinois-administrative-code/title-89-social-services/part-240-community-care-program/subpart-tfinancial-reporting/section-2402040-minimum-direct-service-worker-costs-for-in-home-service, respectively, for more information.

90 percent. If an alternate minimum percentage is recommended, we request that commenters provide the rationale for that minimum percentage.

We considered whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness. However, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce. We request comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities, we request comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services.

We also request comment on the following options for the minimum percentage of payments that must be spent on compensation to direct care workers for each specific service that this provision should apply if this provision should apply to other services at § 440.180(b): (1) 65 percent; (2) 70 percent; (3) 75 percent; and (4) 80 percent. Specifically, we request that commenters respond separately on the minimum percentage of payments for services delivered in a non-residential community-based facility, day center, senior center, or other dedicated physical space, which would be expected to have higher other indirect costs and facility costs built into the Medicaid payment rate than other HCBS. If an alternate minimum percentage is recommended, we request that commenters provide the rationale for that minimum percentage.

We further clarify that we are requesting comment on a different range of options for the other services at § 440.180(b) than for the services at § 440.180(b)(2) through (4) because we

expect that some of the other services at § 440.180(b), such as adult day health and day habilitation services, may have higher other indirect costs and facility costs than the services at § 440.180(b)(2) through (4). We also request that commenters respond separately on the minimum percentage of payments for facility-based residential services and other facility-based round-the-clock services that have other indirect costs and facility costs that would be paid for at least in part by room and board payments that Medicaid does not cover. If a minimum percentage is recommended for any services, we request that commenters provide the rationale for that minimum percentage.

At § 441.302(k)(1)(i), we propose to define compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778), and benefits (such as health and dental benefits, sick leave, and tuition reimbursement). In addition, we propose to define compensation to include the employer share of payroll taxes for direct care workers delivering services under section 1915(c) waivers. We considered whether to include training or other costs in our proposed definition of compensation. However, we determined that a definition that more directly assesses the financial benefits to workers would better ensure that a sufficient portion of the payment for services went to direct care workers, as it is unclear that the cost of training and other workforce activities is an appropriate way to quantify the benefit of those activities for workers. We request comment on whether the definition of compensation should include other specific financial and non-financial forms of compensation for direct care workers.

At § 441.302(k)(1)(ii), we propose to define direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating) or instrumental activities of daily living (such as cooking, grocery shopping, managing finances), and provide behavioral supports, employment supports, or other services to promote community integration. Specifically, we propose to define direct care workers to include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who

provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration. We further identify that our definition of direct care worker is intended to exclude nurses in supervisory or administrative roles who are not directly providing nursing services to people receiving HCBS.

Our definition of direct care worker is intended to broadly define such workers to ensure that the definition appropriately captures the diversity of roles and titles that direct care workers may have. We included workers with professional degrees, such as nurses, in our proposed definition because of the important roles that direct care workers with professional degrees play in the care and services of people receiving HCBS, and because excluding workers with professional degrees may increase the complexity of reporting, and may unfairly punish States, managed care plans, and providers that disproportionately rely on workers with professional degrees in the delivery of HCBS. We also propose to define direct care workers to include: individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model. This proposed definition is in recognition of the varied service delivery models and employment relationships that can exist in HCBS waivers. We request comment on whether there are other specific types of direct care workers that should be included in the definition, and whether any of the types of workers listed should be excluded from the definition of direct care worker.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. At § 441.302(k)(2), under our authority at

section 1902(a)(6) of the Act, we propose to require that States demonstrate that they meet the minimum performance level at § 441.302(k)(3)(i) through new Federal reporting requirements at § 441.311(e). We discuss these reporting requirements in our discussion of proposed § 441.311(e).

At § 441.302(k)(4), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for "consistent administration" should require consistency between these two modes of service delivery. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.302(k) with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because workforce shortages exist under other HCBS authorities, which include many of the same types of services to address activities of daily living or instrumental activities of daily living as under section 1915(c) waiver authority, we are proposing to incorporate these requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements at § 441.302(k) to section 1915 (j), (k), and (i) State plan services by cross-referencing at §§ 441.464(f), 441.570(f), and 441.745(a)(1)(vi), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(30)(A) of the Act to ensure payments to HCBS providers are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available to beneficiaries at least to the extent as to the general population in the same geographic area. We believe the same arguments

for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of payment adequacy provisions across section 1915(i), (j), and (k) authorities. As noted earlier in section II.B.4. of this proposed rule, to accommodate the addition of new language at §§ 441.464(e) and 441.464(f), we are proposing to renumber existing § 441.464(e) as § 441.464(g) and existing § 441.464(f) as § 441.464(h). We request comment on whether we should exempt, from these requirements, services delivered using any self-directed service delivery model under any Medicaid authority.

We considered whether to also apply these proposed payment adequacy requirements to section 1905(a) "medical assistance" State plan personal care and home health services. However, we are not proposing that these requirements apply to any 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for section 1915(c), (i), (j), waiver programs and section 1915(i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authorities. We request comment on whether we should apply these requirements to section 1905(a) State plan personal care and home health services.

As noted throughout the HCBS provisions in this preamble, we recognize that many States may need time to implement these requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these proposed payment adequacy requirements. We expect that these activities will take longer than similar activities for other HCBS provisions in this proposed rule. Further, we expect that it will take a substantial amount of time for managed care plans and providers to establish the necessary systems, data collection tools, and processes necessary to

collect the required information to report to States. As a result, we are proposing at § 441.302(k)(4), to provide States with 4 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 4 years after the effective date of the final rule to implement these requirements. Similar to our rationale in other sections, this proposed timeline reflects feedback from States and other interested parties that it could take 3 to 4 years for States to complete any necessary work to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of the proposals outlined in this section. We also considered the overall burden of the proposed rule as whole in proposing the effective date for the payment adequacy provision. We invite comments on the overall burden associated with implementing this section, whether this timeframe is sufficient, whether we should require a shorter timeframe (such as 3 years) or longer timeframe (such as 5 years) to implement the payment adequacy provisions and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

6. Supporting documentation required (§ 441.303(f)(6))

As described in section II.B.7 of this proposed rule, discussing newly proposed reporting requirements, States vary in whether they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. While some States require individuals to first be determined eligible for waiver services to join the waiting list, other States permit individuals to join a waiting list after an expression of interest in receiving waiver services. This can

overestimate the number of people who need Medicaid-covered HCBS because the waiting lists may include individuals who are not eligible for services. According to the Kaiser Family Foundation, over half of people on HCBS waiting lists live in States that do not screen people on waiting lists for eligibility.⁸³

We have not previously required States to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI⁸⁴ discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists. In addition, we have found, over the past several years in particular, that some States are operating waiting lists for their section 1915(c) waiver programs even though they are serving fewer people than their CMS-approved enrollment limit or cap, and States are expected to enroll individuals up to their CMS-approved enrollment limit or cap before imposing a waiting list. However, because we do not routinely collect information on States' use of waiting lists and the number of people on waiting lists, we are unable to determine the extent to which States are operating such "unauthorized" waiting lists or to work with States to address these "unauthorized" waiting lists.

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Based on the authority found at section 1902(a)(6) of the Act, we now propose to require information from States on waiting lists to improve public transparency and processes related to States' HCBS waiting lists and ensure that

⁸³ Burns, A., M. O'Malley Watts, M. Ammula. A Look at Waiting lists for Home and Community-Based Services from 2016 to 2021. Kaiser Family Foundation. https://www.kff.org/47f8e6f/.

⁸⁴ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

we are able to adequately oversee and monitor States' use of waiting lists in their section 1915(c) waiver programs. To address new proposed requirements at § 441.311(d)(1), described in the next section of the preamble, on State reporting on waiting lists, we propose to amend § 441.303(f)(6) by adding the following sentence to the end of the existing regulatory text: If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1)."

7. Reporting Requirements (§§ 441.311, 441.474(c), 441.580(i), and 441.745(a)(1)(vii))

Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. As discussed in section II.B.1. of this proposed rule, in 2014, we released guidance for section 1915(c) waiver programs in which we requested States to report on State-developed performance measures across several domains, as part of an overarching HCBS waiver quality strategy. The 2014 guidance established an expectation that States conduct systemic remediation and implement a Quality Improvement Project when they score below 86 percent on any of their performance measures. Under our authority at section 1902(a)(6) of the Act, we are proposing requirements at § 441.311, in combination with other proposed requirements identified throughout this proposed rule, to supersede and fully replace the reporting metrics and the minimum 86 percent performance level expectations for States' performance measures described in the 2014 guidance. We describe the basis and scope of this section in paragraph (a).

The reporting requirements proposed in this proposed rule represent consolidated feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties on improving and enhancing section 1915(c) waiver performance to integrate nationally standardized quality measures into the reporting requirements, address gaps in existing

reporting requirements related to access and the direct service workforce, strengthen health and welfare and person-centered planning reporting requirements, and eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. We believe that the proposed reporting requirements will allow us to better assess State compliance with the statutory and regulatory requirements for section 1915(c) waiver programs. As indicated at the end of this preamble section, we propose that the following reporting requirements also apply to State plan options authorized under section 1915(i), (j) and (k) of the Act, as well as to both FFS and managed care delivery systems.

a. Compliance Reporting

(1) Incident Management System Assessment

As noted earlier in section II.B.3. of this preamble, there have been notable and high-profile instances of abuse and neglect in recent years that highlight the risks associated with poor quality care and with inadequate oversight of HCBS in Medicaid, despite State efforts to implement statutory and regulatory requirements to protect the health and welfare of individuals receiving section 1915(c) waiver program services, and State adoption of related subregulatory guidance, requirements, and adopting subregulatory guidance. In addition, a July 2019 survey of States that operate section 1915(c) waivers found that:

- Definitions of critical incidents vary across States and, in some cases, within States for different HCBS programs or populations;
- Some States do not use standardized forms for reporting incidents, thereby impeding the consistent collection of information on critical incidents;
- Some States do not have electronic incident management systems, and, among those that do, many use systems with outdated electronic platforms that are not linked with other State systems, leading to the systems operating in silos and the need to consolidate information across disparate systems; and

• Many States cited the lack of communication within and across State agencies, including with investigative agencies, as a barrier to incident resolution.

Based on these findings and reports, as well as feedback obtained during various public engagement activities conducted with interested parties over the past several years to standardize and strengthen health and welfare reporting requirements, we are proposing new requirements for States' incident management systems at § 441.302(a)(6), as discussed in section II.B.3. of this preamble. We believe that these proposed reporting requirements will allow us to better assess State compliance with the requirements at § 441.302(a)(6).

Relying on our authority at section 1902(a)(6) of the Act, at § 441.311(b), we propose to establish new compliance reporting requirements. Specifically, at § 441.311(b)(1)(i), we propose to require that States report every 24 months on the results of an incident management system assessment to demonstrate that they meet the requirements at § 441.302(a)(6) that the State operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents, including that:

- The State define critical incidents to meet the proposed minimum standard definition at § 441.302(a)(6)(i)(A);
- The State have an electronic critical incident system that, at a minimum, enables electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents as proposed at § 441.302(a)(6)(i)(B);
- The State require that providers report any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(C);
- The State use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and

occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services, as proposed at § 441.302(a)(6)(i)(D);

- The State share information on reported incidents, the status and resolution of investigations, such as through the use of information sharing agreements, with other entities in the State responsible for investigating critical incidents, if the State refers critical incidents to other entities for investigation, as proposed at § 441.302(a)(6)(i)(E); and
- The State separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes as proposed at § 441.302(a)(6)(i)(F).

Given the risk of preventable and intentional harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believe the requirement for States to report every other year on the results of an incident management system assessment is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. In the absence of such a reporting requirement, we are unable to determine whether States have effective systems in place to identify and address incidents of abuse, neglect, exploitation, or other harm during the course of service delivery; ensure that States are protecting the health and welfare of individuals receiving section 1915(c) waiver program services; and safeguard people receiving section 1915(c) waiver program services from preventable or intentional harm.

In proposing an every other year timeframe for reporting, we were attempting to take into account the likely frequency of State changes to policies, procedures, and information systems, while also balancing State reporting burden and the potential risk to beneficiaries if States have incident management systems that are not compliant with the proposed requirements at § 441.302(a)(6). We believe every other year timeframe for reporting is sufficient to detect

substantial changes to policies, procedures, and information systems and ensure that we have accurate information on States' incident management systems. We also propose, at § 441.311(b)(1)(ii), to allow States to reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined to meet the requirements at proposed § 441.302(a)(6). We expect to provide States with technical assistance on how to meet the requirements at proposed § 441.302(a)(6). We invite comments on whether the timeframe for States to report on the results of the incident management system assessment is sufficient or if we should require reporting more frequently (every year) or less frequently (every 3 years). We also invite comment on whether we should require reporting more frequently (every 3 years or every 4 years) for States that are determined to have an incident management system that meets the requirements at § 441.302(a)(6). If an alternate timeframe is recommended, we request that commenters provide the rationale for that alternate timeframe.

(2) Critical Incidents

As discussed earlier in section II.B.4. of this proposed rule, at § 441.302(a)(6)(i)(A), we propose to require States to define critical incidents at a minimum as verbal, physical, sexual, psychological, or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; a medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or an unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect.

Based on the same rationale as discussed previously in section II.B.7.a.(1) of this preamble related to the proposed incident management system assessment proposed reporting requirement, at § 441.311(b)(2), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States report annually on the number and percent of critical incidents for which an investigation was initiated within State-specified timeframes; number and percent of critical incidents that are investigated and for which the State determines the resolution within

State-specified timeframes; and number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes. We intend to use the information generated from the proposed reporting requirements at § 441.311(b)(2)(ii) through (iv) to determine if States meet the requirements at § 441.302(a)(6)(ii). Given the risk of harm to beneficiaries when effective incident management systems are not in place, documented instances of abuse and neglect among people receiving HCBS, and identified shortcomings and weaknesses of States' incident management systems discussed earlier, we believe the proposed requirement at § 441.311(b)(2) for States to report annually on critical incidents is in the best interest of and necessary for protecting the health and welfare of individuals receiving section 1915(c) waiver program services. We invite comments on the timeframe for States to report on the critical incidents, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

(3) Person-Centered Planning

Under the authority of section 1902(a)(6) of the Act, we propose at § 441.311(b)(3) to require that States report annually to demonstrate that they meet the requirements at § 441.301(c)(3)(ii). Specifically, at § 441.311(b)(3)(i), we propose to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. At § 441.311(b)(3)(ii), we propose to require that States report on the percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. These proposed requirements are based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance. As discussed in section II.B.7. of this preamble, this feedback has indicated that we should strengthen person-centered planning reporting requirements, and

eliminate annual performance measure reporting requirements that provide limited useful data for assessing State compliance with statutory and regulatory requirements. These proposed requirements are also based on feedback received through the RFI⁸⁵ discussed earlier about the need to standardize reporting and set minimum standards for HCBS.

As discussed in section II.B.1. of this preamble, we are proposing a revision to the regulatory text so that it is clear that changes to the person-centered service plan are not required if the re-assessment does not indicate a need for changes. As such, for the purpose of the reporting requirement at § 441.311(b)(3)(ii), beneficiaries will be considered to have had a service plan updated as a result of the re-assessment if it is documented that the required re-assessment did not indicate a need for changes.

For both of the metrics at § 441.301(c)(3), we propose to allow States to report on a statistically valid random sample of beneficiaries, rather than for all individuals continuously enrolled in the waiver program for at least 365 days. We invite comments on whether there are other specific compliance metrics related to person-centered planning that we should require States to report, either in place of or in addition to the metrics we proposed. We also invite comments on the timeframe for States to report on the person-centered planning, whether we should require reporting less frequently (every 2 years), and if an alternate timeframe is recommended, the rationale for the alternate timeframe.

(4) Type, Amount, and Cost of Services

As discussed previously in section II.B.4. of this preamble, we propose to amend § 441.302(h) to avoid duplicative or conflicting reporting requirements with the new *Reporting Requirements* section at proposed § 441.311. In particular, at § 441.302(h), we propose to remove paragraphs (1) and (2). At § 441.311(b)(4), we propose to add the language previously at § 441.302(h)(1). In doing so, we are proposing to retain the current requirement that States

⁸⁴ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

report on the type, amount, and cost of services and to include the reporting requirement in the new consolidated reporting section at § 441.311.

b. Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set

At § 441.311(c), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States report every other year on the HCBS Quality Measure Set, which is described later in section II.B.8. of the preamble. Specifically, we propose, at § 441.311(c)(1)(i), to require that States report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the HCBS Quality Measure Set described later in section II.B.8. of the preamble, on measures identified in the HCBS Quality Measure Set as mandatory measures for States to report or are identified as measures for which the Secretary will report on behalf of States, and, at § 441.311(c)(1)(ii), to allow States to report on measures in the HCBS Quality Measure Set that are not identified as mandatory, as described later in this section of this proposed rule. We are proposing every other year for State reporting in recognition of the fact that the current, voluntary HCBS Quality Measure Set is heavily comprised of survey-based measures, which are more burdensome, including for beneficiaries who would be the respondents for the surveys, and costlier to implement than other types of quality measures. Further, we believe that requiring reporting every other year, rather than annually, would better allow States to use the data that they report for quality improvement purposes, as it would provide States with sufficient time to implement interventions that would result in meaningful improvement in performance scores from one reporting period to another. We are also proposing this frequency in recognition of the overall burden of the proposed requirements.

As discussed earlier in section II.B.1. of this preamble, section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplification, simplicity of administration, and in the best interest of Medicaid beneficiaries. Because the

delivery of high quality services is in the best interest of Medicaid beneficiaries, we propose at § 441.311(c)(1)(iii), under our authority at section 1902(a)(19) of the Act, to require States to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures. We welcome comments on whether there should be a threshold of compliance that would exempt the State from developing improvement strategies, and if so, what that threshold should be.

At § 441.311(c)(1)(iv), we propose to allow States to establish State performance targets for other measures in the HCBS Quality Measure Set that are not identified as mandatory for States to report or as measures for which the Secretary will report on behalf of States as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those targets.

At § 441.311(c)(2), we propose to report, on behalf of the States, on a subset of measures in the HCBS Quality Measure Set that are identified as measures for which we will report on behalf of States. Further, at § 441.311(c)(3), we propose to allow, but not require, States to report on measures that are not yet required but will be, and on populations for whom reporting is not yet required but will be phased-in in the future.

We invite comments on whether the timeframe for States to report on the measures in HCBS Quality Measure Set is sufficient, whether we should require reporting more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We welcome comments on any additional changes we should consider in this section.

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⁸⁶ We note that compliance with CMS regulations and reporting requirements does not imply that a State has complied with the integration mandate of Title II of the ADA, as interpreted by the Supreme Court in the Olmstead Decision.

c. Access Reporting

As noted earlier in section II.B.6. of this preamble, feedback obtained during various public engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI⁸⁷ discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists and for standardized reporting on HCBS access, including timeliness of HCBS and the comparability to services received to eligibility for services.

At § 441.311(d)(1)(i), relying on our authority under section 1902(a)(6) of the Act, we propose to require that States provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program, if they have a limit on the size of the waiver program and maintain a list of individuals who are waiting to enroll in the waiver program, as described in § 441.303(f)(6). We further propose to require that this description must include, but be not limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screens individuals on the waiver list for eligibility, and the frequency of re-screening if applicable. We also propose to require States to report, at § 441.311(d)(1)(ii), the number of people on the waiting list, if applicable, and, at § 441.311(d)(1)(iii), the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable. We invite comments on whether there are other specific metrics or reporting requirements related to waiting lists that we should require States to report, either in place of or in addition to the requirements we proposed. We also invite comments on the timeframe for States to report on their waiting lists, whether we should require reporting less

⁸⁷ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see: https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.311(d)(2)(i), based on our authority under section 1902(a)(6) of the Act, we propose to require States report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. We propose to focus on these specific services for this reporting requirement because of feedback from States, consumer advocates, managed care plans, providers, and other HCBS interested parties that timely access to these services is especially challenging and because the failure of States to ensure timely access to these services poses substantial risk to the health, safety, and quality of care of individuals residing independently and in other community-based residences. Having States report this information will assist us in our oversight of State HCBS programs by helping us target our technical assistance and monitoring efforts. We request comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

For this metric, we propose to allow States to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months, rather than for all individuals newly approved to begin receiving these services within the past 12 months. We invite comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invite comments on whether there are other specific metrics related to the amount of time that it takes for eligible individuals to begin receiving homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed.

At § 441.311(d)(2)(ii), also based on our authority under section 1902(a)(6) of the Act, we propose to require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. For this metric, we further propose to allow States to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these services within the past 12 months. We invite comments on the timeframe for States to report on this metric, whether we should require reporting less frequently (every 2 or 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe. We also invite comments on whether there are other specific metrics related to individuals' use of authorized homemaker services, home health aide services, or personal care services that we should require States to report, either in place of or in addition to the metric we proposed. We further request comment on whether this requirement should apply to additional services authorized under section 1915(c) of the Act.

d. Payment Adequacy

At § 441.311(e), we propose new reporting requirements for section 1915(c) waivers, under our authority at section 1902(a)(6) of the Act, for States to demonstrate that they meet the proposed *HCBS Payment Adequacy* requirements at § 441.302(k). Specifically, we propose that States report annually on the percent of payments for homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4), that are spent on compensation for direct care workers. As discussed in section II.B.5. of this preamble, we have focused this requirement on homemaker services, home health aide services, and personal care services because they are services for which we expect that the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. These are services that would most commonly be conducted in individuals'

homes and general community settings. As such, there should be low facility or other indirect costs associated with the services.

We considered whether the proposed reporting requirements at § 441.311(e) related to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services for individuals with chronic mental illness. As discussed in section II.B.5. of this preamble, these services may have facility or other indirect costs for which we do not have adequate information to determine a minimum percent of the payment that should be spent on compensation for the direct care workforce and, as a result, we are not proposing to apply HCBS Payment Adequacy requirements at § 441.302(k) to services other than homemaker, home health aide, and personal care services, as listed at § 440.180(b)(2) through (4). However, we are requesting comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to other services listed at § 440.180(b). In particular, we are requesting comment on whether the proposed requirements at § 441.302(k)(3)(i) related to the percent of payments going to the direct care workforce should apply to residential habilitation services, day habilitation services, and home-based habilitation services. As a result, we are also requesting comment whether States should be required to report annually on the percent of payments for other services listed at § 440.180(b) that are spent on compensation for direct care workers and, in particular, on the percent of payments for residential habilitation services, day habilitation services, and home-based habilitation services that are spent on compensation for direct care workers.

We further propose that States separately report for each service subject to the reporting requirement and, within each service, separately report on payments for services that are self-directed. We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance

with the requirement at § 441.302(k) and decided that the proposed requirement would be most effective to demonstrate State compliance. We request comment on whether we should allow States to provide an assurance or attestation, subject to audit, that they meet the requirement in place of reporting on the percent of payments, and whether we should reduce the frequency of reporting to every other year.

The intent of this proposed requirement is for States to report in the aggregate for each service across all of their services across all programs as opposed to separately report for each waiver or HCBS program. As an alternative, we considered whether to require reporting at the delivery system, HCBS waiver program, or population level. However, we are not proposing to require additional levels of reporting because we expect that it would increase reporting burden for States without providing us with additional information necessary for determining whether States meet the requirements at § 441.302(k). We request comment on whether we should require States to report on the percent of payments for certain HCBS that are spent on compensation for direct care workers at the delivery system, HCBS waiver program, or population level. In addition, we considered whether to require States to report on median hourly wage and on compensation by category, including salary, wages, and other remuneration; benefits; and payroll taxes. We believe that such information would be valuable for better monitoring workforce compensation and its impact on workforce shortages and turnover and access to services for Medicaid beneficiaries. While such information should be readily accessible for providers, we have not proposed requiring these types of reporting, as collecting and aggregating such information would increase State burden. We request comment on whether we should require States to report on median hourly wage and on compensation by category. We considered whether to allow States, at their option, to exclude, from their reporting to CMS but not from the proposed requirement at § 441.302(k) related to the percent of payments that are spent on compensation for direct care workers, payments to providers of agency-directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries.

based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service. We considered this option as a way to reduce State, managed care plan, and provider data collection and reporting burden based on the experience of States that have implemented similar reporting requirements. However, we are concerned that such an option could discourage providers from serving Medicaid beneficiaries or increasing the number of Medicaid beneficiaries or amount of Medicaid revenues. We request comment on whether we should allow States the option to exclude, from their reporting to CMS, payments to providers of agency directed services that have low Medicaid revenues or serve a small number of Medicaid beneficiaries, based on Medicaid revenues for the service, number of direct care workers serving Medicaid beneficiaries, or the number of Medicaid beneficiaries receiving the service.

We also request comment on whether we should establish a specific limit on this exclusion and, if so, the specific limit we should establish, such as to limit the exclusion to providers in the lowest 5th, 10th, 15th, or 20th percentile of providers in terms Medicaid revenues for the service, number of Medicaid beneficiaries served, or number of direct care workers serving Medicaid beneficiaries.

We also considered whether to allow States to exclude payments for self-directed services from this reporting requirement, based on feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years related to HCBS workforce shortages that indicate that compensation for direct care workers in self-directed models tends to be higher and may comprise a higher percentage of the payments for services than other HCBS, and that administrative costs account for a small percentage of the cost of self-directed services. However, we have decided that payments for self-directed services by States should be included in these reporting requirements. This decision not to exclude them was based on the importance of ensuring a sufficient direct care workforce for self-directed services, the experience of States that have applied similar requirements to

report on the percent of payments for to self-directed services that are spent on compensation for direct care workers, and the lack of conclusive data indicating that compensation for direct care workers meets or exceeds the proposed 80 percent threshold. We request comment on whether we should allow States to exclude payments for self-directed services from these reporting requirements.

e. Effective Date

We recognize that many States may need time to implement these reporting requirements, including to amend provider agreements or managed care contracts, make State regulatory or policy changes, implement process or procedural changes, update information systems for data collection and reporting, or conduct other activities to implement these requirements. As a result, we are proposing at § 441.311(f)(1) to provide States with 3 years to implement the compliance reporting requirements at § 441.311(b), the HCBS Quality Measure Set reporting requirements at § 441.311(c), and the access reporting requirements at § 441.311(d) in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based on feedback from States and other interested parties that it could take 2 to 3 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these proposed reporting requirements. We also have considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (2 years) or longer timeframe (4 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

In addition, we are proposing at § 441.311(f)(2) to provide States with 4 years to implement the payment adequacy reporting requirements at § 441.311(e) in FFS delivery systems following the effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 4 years after the effective date of the final rule to implement these requirements. This time period is intended to align with the effective date for the HCBS payment adequacy requirements at § 441.302(k), which are discussed in section II.B.5. of this preamble. It is also based on feedback from States and other interested parties that it could take 3 to 4 years to amend State regulations and work with their State legislatures, if needed, as well as to revise policies, operational processes, information systems, and contracts to support implementation of these reporting requirements. We also have considered all of the HCBS proposals outlined in this proposed rule as whole. We invite comments on whether this timeframe is sufficient, whether we should require a shorter timeframe (3 years) or longer timeframe (5 years) to implement these provisions, and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.311(f), we propose to apply all of the reporting requirements described in § 441.311 to services delivered under FFS and managed care delivery systems. As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs, and as noted in the Medicaid context this would include consistent administration between FFS and managed care programs. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.302(a)(6) with respect to HCBS delivered both under FFS and managed care delivery systems.

As discussed earlier in section II.B.1. of this preamble, the proposed requirements at § 441.311, in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace the reporting expectations and the minimum 86 percent performance level for State's performance measures described in the 2014 guidance, also discussed earlier in section II.B.1. of this preamble. We expect that States may implement some of the requirements proposed in this proposed rule in advance of any effective date. If the rule is finalized, we will work with States to phase out the 2014 guidance as they implement the requirements in the future final rule to reduce unnecessary burden and to avoid duplicative or conflicting reporting requirements.

In accordance with the requirement of section 2402(a)(3)(A) of the Affordable Care Act for States to achieve a more consistent administration of policies and procedures across HCBS programs, and because these reporting requirements are relevant to other HCBS authorities, we are proposing to incorporate these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we propose to apply the requirements at § 441.311 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.474(c), 441.580(i), and 441.745(a)(1)(vii), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities. To accommodate the addition of new language at § 441.580(i), we are proposing to renumber existing § 441.580(i) as § 441.580(j).

We considered whether to also apply these reporting requirements to section 1905(a) "medical assistance" State plan personal care, home health, and case management services. However, we are not proposing that these requirements apply to any section 1905(a) State plan services based on State feedback that they do not have the same data collection and reporting capabilities in place for section 1905(a) services as they do for sections 1915(c), (i), (j), and (k) services and because the person-centered planning, service plan, and waiting list requirements that comprise a significant portion of these reporting requirements have little to no relevance for section 1905(a) services, in comparison to section 1915(c), (i), (j), and (k) services. Further, the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k) authorities, while only a small percentage of HCBS nationally is delivered under section 1905(a) State plan authority. We request comment on whether we should establish similar reporting requirements for section 1905(a) "medical assistance" State plan personal care, home health, and case management services.

We expect that, should we finalize these reporting requirements, we will establish new processes and forms for States to meet the reporting requirements, provide additional technical information on how States can meet the reporting requirements including related to sampling requirements (where States are permitted to report on a sample of beneficiaries rather than on all individuals who meet the inclusion criteria for the reporting requirement), and amend existing templates and establish new templates under the Paperwork Reduction Act.

8. Home and Community-Based Services (HCBS) Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)

On July 21, 2022, we issued State Medicaid Director Letter # 22-00388 to release the first official version of the HCBS Quality Measure Set. The HCBS Quality Measure Set is a set of nationally standardized quality measures for Medicaid-covered HCBS. It is intended to promote

⁸⁸ CMS State Medicaid Director Letter. SMD# 22-003 Home and Community-Based Services Quality Measure Set. July 2022. Accessed at https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.

more common and consistent use within and across States of nationally standardized quality measures in HCBS programs, create opportunities for CMS and States to have comparative quality data on HCBS programs, drive improvement in quality of care and outcomes for people receiving HCBS, and support States' efforts to promote equity in their HCBS programs. It is also intended to reduce some of the burden that States and other interested parties may experience in identifying and using HCBS quality measures. By providing States and other interested parties with a set of nationally standardized measures to assess HCBS quality and outcomes and by facilitating access to information on those measures, we believe that we can reduce the time and resources that States and other interested parties expend on identifying, assessing, and implementing measures for use in HCBS programs.

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Under our authority at sections 1102(a) and 1902(a)(6) of the Act, we are proposing to add a new section, at § 441.312, *Home and Community-Based Services Quality Measure Set*, to require use of the measure set in 1915(c) waiver programs and promote public transparency related to the administration of Medicaid-covered HCBS. We describe the basis and scope of this section in proposed paragraph (a).

We believe that quality is a critical component of efficiency, and as such, having a standardized set of measures that is used to assess the quality of Medicaid HCBS programs supports the efficient operation of the Medicaid program. Further, we believe that this proposal is necessary for the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act, consistent with section 1902(a)(4) of the Act, as it would establish a

process through which we would regularly update and maintain the required set of measures at § 441.311(c) in consultation with States and other interested parties (as described later in this section of the preamble). This process would ensure that the priorities of interested parties are reflected in the selection of the measures included in the HCBS Quality Measure Set. This process would also ensure that the required set of HCBS quality measures is updated to address gaps in the HCBS Quality Measure Set as new measures are developed and to remove measures that are less relevant or add less value than other available measures, and that it meets scientific and other standards for quality measures. Due to the constantly evolving field of HCBS quality measurement, we believe that the failure to establish such a process would result in ongoing reporting by States of measures that do not reflect the priorities of interested parties, measures that offer limited value compared to other measures, and measures that do not meet strong scientific and other standards. It would also result in a lack of reporting on key measurement priority areas, which could be addressed by updating the HCBS Quality Measure Set as new measures are developed. The failure to establish such a process would lead to inefficiency in States' HCBS quality measurement activities through the continued reporting on an outdated set of measures. In other words, we believe that such a process is necessary for the efficient administration of Medicaid-covered HCBS by ensuring that quality measure reporting requirements are focused on the most valuable, useful, and scientifically supported areas of quality measurement, and that quality measures with limited value are removed timely from quality measure reporting requirements.

We propose a definition at § 441.312(b)(1) for "Attribution rules," to mean the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the "HCBS Quality Measure Set" as described in proposed § 441.312(d)(6), and at § 441.312(b)(2) for "Home and Community-Based Services Quality Measure Set" to mean the Home and Community-Based Measures for Medicaid

established and updated at least every other year by the Secretary through a process that allows for public input and comments, including through the **Federal Register**.

At § 441.312(c), we describe the general process that the Secretary will follow to update and maintain the HCBS Quality Measure Set. Specifically, at § 441.312(c)(1), we propose that the Secretary will identify and update at least every other year, through a process that allows for public input and comment, the quality measures to be included in the HCBS Quality Measure Set. At § 441.312(c)(2), we propose that the Secretary will solicit comment at least every other year with States and other interested parties, which are identified later in this section of the preamble, to:

- Establish priorities for the development and advancement of the HCBS Quality Measure Set.
- Identify newly developed or other measures which should be added including to address gaps in the measures included in the HCBS Quality Measure Set.
- Identify measures which should be removed as they no longer strengthen the HCBS
 Quality Measure Set.
- Ensure that all measures included in the HCBS Quality Measure Set are evidence-based, are meaningful for States, and are feasible for State-level and program-level reporting as appropriate.

The proposed frequency for updating the quality measures included in the HCBS Quality Measure Set is aligned with the proposed frequency at § 441.311(c)(1)(i) for States' reporting of the measures in the HCBS Quality Measure Set. We have based other aspects of the process that the Secretary will follow to update and maintain the HCBS Quality Measure Set in part on the proposed processes for the Secretary to update and maintain the Child, Adult, and Health Home Core Sets as described in the Medicaid Program and CHIP; Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting proposed rule (87 FR 51303); (hereinafter the "Mandatory Medicaid and CHIP Core Set Reporting proposed rule"). We believe that such

alignment in processes will ensure consistency and promote efficiency for both CMS and States across Medicaid quality measurement and reporting activities.

At § 441.312(c)(3), we propose that the Secretary will, in consultation with States and other interested parties (as described later in this section of preamble), develop and update the measures in the HCBS Quality Measure Set, at least every other year, through a process that allows for public input and comment. We invite comments on whether the timeframes for updating the measures in the HCBS Quality Measure Set and conducting the process for developing and updating the HCBS Quality Measure Set is sufficient, whether we should conduct these activities more frequently (every year) or less frequently (every 3 years), and if an alternate timeframe is recommended, the rationale for that alternate timeframe.

At § 441.312(d), we describe the proposed process for developing and updating the HCBS Quality Measure Set. Specifically, we propose that the Secretary will address the following through the proposed process:

- Identify all measures in the HCBS Quality Measure Set, including newly added measures, measures that have been removed, mandatory measures, measures that the Secretary will report on States' behalf, measures that States can elect to have the Secretary report on their behalf, as well as the measures that the Secretary will provide States with additional time to report and the amount of additional time.
 - Inform States how to collect and calculate data on the measures.
 - Provide a standardized format and reporting schedule for reporting the measures.
 - Provide procedures that States must follow in reporting the measure data.
- Identify specific populations for which States must report the measures, including people enrolled in a specific delivery system type, people who are dually eligible for Medicare and Medicaid, older adults, people with physical disabilities, people with intellectual or developmental disabilities, people who have serious mental illness, and people who have other

health conditions; and provide attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population.

- Identify the subset of measures that must be stratified by race, ethnicity, Tribal status, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the Secretary.
 - Describe how to establish State performance targets for each of the measures.

We anticipate that, for State reporting on the measures in the HCBS Quality Measure Set, as outlined in § 441.311, the technical information on attribution rules described at proposed § 441.312(d)(6), would call for inclusion in quality reporting based on a beneficiary's continuous enrollment in the Medicaid waiver. This would ensure the State has enough time to furnish services during the measurement period. In the technical information, we anticipate we would set attribution rules to address transitions in Medicaid eligibility, enrollment in Medicare, or transitions between different delivery systems or managed care plans, within a reporting year, for example, based on the length of time beneficiaries was enrolled in each. We invite comment on other considerations we should address in the attribution rules or other topics we should address in the technical information.

At § 441.312(e), we propose, in the process for developing and updating the Home and Community-Based Services Quality Measure Set described at proposed § 441.312(d), that the Secretary consider the complexity of State reporting and allow for the phase-in over a specified period of time of mandatory State reporting for some measures and of reporting for certain populations, such as older adults or people with intellectual and disabilities. At § 441.312(f), we propose that, in specifying the measures and the factors by which States must report stratified measures, the Secretary will consider whether such stratified sampling can be accomplished based on valid statistical methods, without risking a violation of beneficiary privacy, and, for measures obtained from surveys, whether the original survey instrument collects the variables or factors necessary to stratify the measures. This proposed stratification of data for the measures

contained in the HCBS Quality Measure Set is consistent with our statutory authority under section 1902(a)(6) of the Act, which requires States to report information "in such form and containing such information" as the Secretary requires.

Stratified sampling is a method of sampling from a population, in which the sampling can be partitioned into sub-populations, such as by race, ethnicity, sex, age, rural/urban status, disability, language, or such other factors. Stratified data would enable us and States to identify the health and quality of life outcomes of underserved populations and potential differences in outcomes based on race, ethnicity, sex, age, rural/urban status, disability, language, or such factors on measures contained in the HCBS Quality Measure Set. Measuring health disparities, reporting these results, and driving improvements in quality are cornerstones of the CMS approach to advancing health equity. Advancing equity for underserved populations through data reporting and stratification aligns with EO 13985.89 In line with the policy objective of EO 13985, CMS defines health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."90 We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health and quality of life outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that all individuals need to thrive.

We considered giving States the flexibility to choose which measures they would stratify and by what factors. However, as discussed in the Mandatory Medicaid and CHIP Core Set Reporting rule (87 FR 51313), consistent measurement of differences in health and quality of life outcomes between different groups of beneficiaries is essential to identifying areas for

⁸⁷ Exec. Order No. 13985 (2021), Accessed at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

⁹⁰ CMS definition of health equity. Accessed at https://www.cms.gov/pillar/health-equity.

intervention and evaluation of those interventions.⁹¹ This consistency could not be achieved if each State made its own decisions about which data it would stratify and by what factors.^{92,93}

We recognize that States may be constrained in their ability to stratify measures in the HCBS Quality Measure Set and that data stratification would require additional State resources. There are several challenges to stratification of measure reporting. First, the validity of stratification is threatened when the demographic data are incomplete. Complete demographic information is often unavailable to us and to States due to several factors, including the fact that Medicaid applicants and beneficiaries are not required to provide race and ethnicity data.

Second, when States with smaller populations and less diversity stratify data, it may be possible to identify individual data, raising privacy concerns. Therefore, if the sample sizes are too small, the data would be suppressed, in accordance with the CMS Cell Size Suppression Policy and the data suppression policies for associated measure stewards and therefore not publicly reported to avoid a potential violation of privacy. 94

We also may face constraints in stratifying measures for which we are able to report on behalf of States, as our ability to stratify will be dependent on whether the original dataset or survey instrument: (1) collects the demographic information or other variables needed and (2) has a large enough sample size. The Transformed Medicaid Statistical Information System (T-MSIS), for example, currently has the capability to stratify some HCBS Quality Measure Set measures by sex and urban/rural status, but not by race, ethnicity, or disability status. This is because applicants provide information on sex and urban/rural address, which is reported to T-MSIS by States, whereas applicants are not required to provide information on their race and ethnicity or disability status, and often do not do so. However, we have developed the capacity

⁹¹ Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568-573.

⁹² Centers for Medicare & Medicaid Services (CMS) Office of Minority Health (OMH). Stratified Reporting. 2022; https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/stratified-reporting.

⁹³ National Quality Forum. A Roadmap for Promoting Health Equity and Eliminating Disparities. Sep 2017. Accessed at https://www.qualityforum.org/Publications/2017/09/A_Roadmap_for_Promoting_Health_Equity_and_Eliminating_Disparities_The_Four_I_s_for_Health_Equity.aspx.

⁹⁴CMS Cell Size Suppression Policy, Issued 2020: https://www.hhs.gov/guidance/document/cms-cell-suppression-policy or the cell suppression standards of the associated measure stewards.

to impute race and ethnicity using a version of the Bayesian Improved Surname Geocoding (BISG) method⁹⁵ that includes Medicaid-specific enhancements to optimize accuracy, and are able to stratify by race and ethnicity, urban/rural status, and sex.

The method proposed for this project utilizes State-submitted race/ethnicity data when it is complete and accurate as based on the Medicaid DQ Atlas assessment for a given year. 96

When State-submitted data is missing or inaccurate, imputed results are used to ensure statistical accuracy. Because imputations are only used when self-reported data is missing or States have systematic errors in reporting race and/or ethnicity, millions of self-reported datapoints are preserved and model accuracy is improved. This also reflects that, as the quality of State-submitted data improves, the imputations will be used less frequently. We will release detailed documentation about the methodology used to develop the imputations prior to the release of these results. While complete demographic information for beneficiaries would always be preferable to using imputed model values, reliable techniques to impute values is a substitute to enable identification and analysis of health disparities.

With these challenges in mind, we propose that stratification by States in reporting of HCBS Quality Measure Set data would be implemented through a phased-in approach in which the Secretary would specify which measures and by which factors States must stratify reported measures. In proposed § 441.312(f), States would be required to provide stratified data for 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. We note that the percentages listed here align with the proposed phase-in of equity reporting in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule, although the proposed deadlines for each

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⁹⁵ Elliott, Marc N., et al. "Using the Census Bureau's surname list to improve estimates of race/ethnicity and associated disparities." *Health Services and Outcomes Research Methodology* 9.2 (2009): 69-83.

⁹⁶ Medicaid DQ Atlas. "Race and Ethnicity." https://www.medicaid.gov/dq-atlas/landing/topics/single/map?topic=g3m16&tafVersionId=32.

compliance level would be longer here (87 FR 51314). However, the timeframe associated with each percentage is different from what was proposed in that rule. Specifically, that proposed rule would require States to provide stratified data for 25 percent of measures within 2 years after the effective date of the final rule, 50 percent of measures within 3 years after the effective date of the final rule, and 100 percent of measures within 5 years after the effective date of the final rule.

We propose a slower phase-in for stratification for the measures in the HCBS Quality Measure Set because the HCBS Quality Measure Set was only first released for voluntary use by States in July 2022, while Child, Adult, and Health Home Core Sets voluntary reporting has been in place for a number of years. Further, a substantial portion of the measures included in the HCBS Quality Measure Set, particularly compared to the Child, Adult, and Health Home Core Sets, are derived from beneficiary experience of care surveys, which are costlier to implement than other types of measures. In addition, the slower phase-in is also intended to take into consideration the overall burden of the reporting requirements in this proposed rule.

We have determined that this proposed phased-in approach to data stratification would be reasonable and minimally burdensome, and thus consistent with EO 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (January 20, 2021),⁹⁷ because we are balancing the importance of being able to identify differences in outcomes between populations under these measures with the potential operational challenges that States may face in implementing these proposed requirements.

We recognize that States may need to make enhancements to their data and information systems or incur other costs in implementing the HCBS Quality Measure Set. We remind States that enhanced FFP is available at a 90 percent match rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems,

⁹⁷ Exec. Order No. 13985 (2021), Accessed at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

in accordance with applicable Federal requirements. ⁹⁸ Enhanced FFP at a 75 percent match rate is also available for operations of such systems, in accordance with applicable Federal requirements. ⁹⁹ Receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. ¹⁰⁰ States are also encouraged to advance the interoperable exchange of HCBS data and support quality improvement activities by adopting standards in 45 CFR part 170 and other relevant standards identified in the ISA. ¹⁰¹

We solicit comments on the proposed schedule for phasing in reporting of HCBS Quality Measure Set data. We also seek comment on whether we should phase-in reporting on all of the measures in the HCBS Quality Measure Set.

At § 441.312(g), we propose the list of interested parties with whom the Secretary must consult to specify and update the quality measures established in the HCBS Quality Measure Set. The proposed list of interested parties includes: State Medicaid Agencies and agencies that administer Medicaid-covered HCBS; health care and HCBS professionals who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs; health care and HCBS professionals, providers, and direct care workers who provide services to older adults, children and adults with disabilities and complex medical and behavioral health care needs who live in urban and rural areas or who are members of groups at increased risk for poor outcomes; HCBS providers; direct care workers and organizations representing direct care workers; consumers and national organizations representing consumers; organizations and individuals with expertise in HCBS quality measurement; voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-

⁹⁸ See section 1903(a)(3)(A)(i) of the Act and § 433.15(b)(3), 80 FR 75817 through 75843; https://www.medicaid.gov/state-resourcecenter/faq-medicaid-and-chip-affordable-care-act-implementation/downloads/affordable-care-act-faq-enhancedfunding-for-medicaid.pdf; https://www.medicaid.gov/federal-policy-guidance/downloads/SMD16004.pdf.

⁹⁹ See section 1903(a)(3)(B) and § 433.15(b)(4).

¹⁰⁰ See § 433.112 (b, 80 FR 75841; https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-433/subpart-C.

¹⁰¹ Relevant standards adopted by HHS and identified in the ISA include the USCDI (https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi), eLTSS (https://www.healthit.gov/isa/documenting-care-plans-person-centered-services), and Functional Assessment Standardized Items (https://www.healthit.gov/isa/representing-patient-functional-status-andor-disability).

based measures of health care; measure development experts; and other interested parties the Secretary may determine appropriate.

Because these quality measurement requirements are relevant to other HCBS authorities, we are proposing to incorporate these requirements within the applicable regulatory sections for other HCBS authorities. Specifically, we propose to apply the proposed requirements at § 441.312 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.474(c), 441.585(d), and 441.745(b)(1)(v), respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1902(a)(6) of the Act, which requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across sections 1915(i), (j), and (k) authorities.

9. Website Transparency (§§ 441.313, 441.486, 441.595, and 441.750)

Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Under our authority at section 1102(a) of the Act, we are proposing to add a new section, at § 441.313, titled *Website transparency*, to promote public transparency related to the administration of Medicaid-covered HCBS. As noted earlier in section II.B.8. of this preamble, we believe that quality is a critical component of efficiency, as payments for services that are low quality do not produce their desired effects and, as such, are more wasteful than payments for services that are high quality. However, feedback from interested parties during various public engagement activities over the past several years have indicated that it is difficult to find information on HCBS access, quality, and outcomes in many States. As a result, it is not

possible for beneficiaries, consumer advocates, oversight entities, or other interested parties to hold States accountable for ensuring that services are accessible and high quality for people who need Medicaid HCBS. As a result, we believe that the proposal described immediately below supports the efficient administration of Medicaid-covered HCBS authorized under section 1915(c) of the Act by promoting public transparency and accountability of the quality and performance of Medicaid HCBS systems, as the availability of such information will improve the ability of interested parties to hold States accountable for the quality and performance of their HCBS systems.

Specifically, at § 441.313(a), we propose to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) of this chapter and that provides the results of the reporting requirements under newly proposed § 441.311 (specifically, incident management, critical incident, person centered planning, and service provision compliance data; data on the HCBS Quality Measure Set; access data; and payment adequacy data). We request comment on whether the requirements at § 435.905(b) are sufficient to ensure the availability and the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the availability and accessibility of the information.

At § 441.313(a)(1), we propose to require that the data and information that States are required to report under § 441.311 be provided on one web page, either directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. We request comment on whether States should be permitted to link to web pages of these managed care entities and whether we should limit the number of separate web pages that a State could link to, in place of directly reporting the information on its own web page.

At § 441.313(a)(2), we propose to require that the web page include clear and easy to understand labels on documents and links. We request comment on whether these requirements

are sufficient to ensure the accessibility of the information for people receiving HCBS and other HCBS interested parties and for specific requirements to ensure the accessibility of the information.

At § 441.313(a)(3), we propose to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. We request comment on whether this timeframe is sufficient or if we should require a shorter timeframe (monthly) or a longer timeframe (semi-annually or annually).

At § 441.313(a)(4), we propose to require that States include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

We are also proposing at § 441.313(b) that CMS must report on its CMS website the information reported by States to us under § 441.311. For example, we envision that we will update CMS's website to provide HCBS comparative information reported by States that can be compared to HCBS information shared by other States. We also envision using data from State reporting in future iterations of the CMS Medicaid and CHIP Scorecard. 102

We are proposing at § 441.313(c), to provide States with 3 years to implement these requirements in FFS delivery systems following effective date of the final rule. For States with managed care delivery systems under the authority of sections 1915(a), 1915(b), 1932(a), or section 1115(a) of the Act and that include HCBS in the MCO's, PIHP's, or PAHP's contract, we are proposing to provide States until the first managed care plan contract rating period that begins on or after 3 years after the effective date of the final rule to implement these requirements. This time period is based primarily on the effective date for State reporting at § 441.311. We also have considered all of the HCBS proposals outlined in the proposed rule as

¹⁰² CMS's Medicaid and CHIP Scorecard. Accessed at https://www.medicaid.gov/state-overviews/scorecard/index.html.

whole. We invite comments on whether this timeframe is sufficient, whether we should require a longer timeframe (4 years) to implement these provisions, and if a longer timeframe is recommended, the rationale for that longer timeframe.

As discussed earlier in section II.B.1. of this preamble, section 2402(a)(3)(A) of the Affordable Care Act requires States to improve coordination among, and the regulation of, all providers of Federally and State-funded HCBS programs to achieve a more consistent administration of policies and procedures across HCBS programs. In the context of Medicaid coverage of HCBS, it should not matter whether the services are covered directly on a FFS basis or by a managed care entity to its enrollees. The requirement for "consistent administration" should require consistency between these two modes of service delivery. We accordingly are proposing to specify that a State must ensure compliance with the requirements in § 441.313, with respect to HCBS delivered both under FFS and managed care delivery systems.

Similarly, because we are proposing to apply the reporting requirements at § 441.311 to other HCBS State plan options, we are proposing to incorporate these website transparency requirements within the applicable regulatory sections. Specifically, we propose to apply the proposed requirements of § 441.313 to section 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.486, 441.595, and 441.750, respectively. Consistent with our proposal for section 1915(c) waivers, we propose these requirements based on our authority under section 1102(a) of the Act to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. We believe the same arguments for proposing these requirements for section 1915(c) waivers are equally applicable for these other HCBS authorities. We request comment on the application of these provisions across section 1915(i), (j), and (k) authorities.

10. Applicability of Proposed Requirements to Managed Care Delivery Systems

As discussed earlier in sections II.B.1., II.B.4., II.B.5., II.B.7., and II.J. of this rule, we are proposing to apply the requirements at §§ 441.301(c)(3), 441.302(a)(6), 441.302(k), 441.311,

and 441.313 to both FFS and managed care delivery systems. Although the proposed provisions at §§ 441.301(c)(3), 441.302(a)(6) and (k), 441.311, and 441.313 would apply to LTSS programs that use a managed care delivery system to deliver services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities, we believe incorporating a reference in 42 CFR part 438 would be helpful to States and managed care plans. Therefore, we propose to add a cross reference to the requirements in proposed § 438.72 to be explicit that States that include HCBS in their MCO, PIHP, or PAHP contracts would have to comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6) and (k), 441.311, and 441.313. We believe this would make the obligations of States that implement LTSS programs through a managed care delivery system clear, consistent, and easy to locate. While we believe the list proposed in § 438.72 would help States easily identify the provisions related to LTSS, we identify that a provision specified in any other section of 42 CFR part 438 or any other Federal regulation but omitted from § 438.72, is still in full force and effect. We also note that § 438.208(c)(3)(ii) currently includes a cross-reference to § 441.301(c)(1) and (2). We are not proposing any changes to the regulatory language at § 441.301(c)(1) or (2) or to $\S 438.208(c)(3)(ii)$ through this rule. We have included $\S 441.301(c)(1)$ and (2) in the proposed regulatory language at § 438.72 so that it is clear that the requirements at § 441.301(c)(1) and (2) continue to apply when States include HCBS in their MCO, PIHP, or PAHP contracts.

C. Documentation of access to care and service payment rates (§ 447.203)

Section 1902(a)(30)(A) of the Act requires that State plans "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." Through the proposed provisions in § 447.203, we seek to establish an updated process through which States would be required to document, and we would ensure, compliance with the requirements of section 1902(a)(30)(A) of the Act.

In the 2015 final rule with comment period, we codified a process that requires States to complete and make public AMRPs that analyze and inform determinations of the sufficiency of access to care (which may vary by geographic location in the State) and are used to inform State policies affecting access to Medicaid services, including provider payment rates. The AMRP must specify data elements that support the State's analysis of whether beneficiaries have sufficient access to care, based on data, trends, and factors that measure beneficiary needs, availability of care through enrolled providers, and utilization of services. States are required to update their AMRPs at regular intervals and whenever the State proposes to reduce FFS provider payment rates or restructure them in circumstances when the changes could result in diminished access. Specifically, the current AMRP process at § 447.203 requires States to consider the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The analysis further requires consideration of beneficiary and provider input, and an analysis of the percentage comparison of Medicaid payment rates to other public and private health insurer payment rates within geographic areas of the State, for each of the services reviewed, by the provider types and sites of service. While the current regulations do include broad requirements for what an acceptable analysis methodology must include, States retain discretion in establishing their processes, including but not limited to the specification of data sources and analytical methodologies to be used. The result is a large analytical burden on States without a standardization that would allow us and other interested parties to compare data between States to understand whether the Federal access standards are

successfully achieving robust access consistent with section 1902(a)(30)(A) of the Act for beneficiaries nationwide.

Through AMRPs, we aimed to create a transparent and data-driven process through which to ensure State compliance with section 1902(a)(30)(A) of the Act. Following publication of the 2011 proposed rule and as discussed in both the 2015 final rule with comment period and the 2016 final rule, as we worked with States to implement the AMRP requirements, many States expressed numerous concerns about the rule. 103,104,105 States were concerned about the administrative burden of completing the AMRPs and questioned whether the AMRP process is the most effective way to establish that access to care in a State's Medicaid program meets statutory requirements. States with high managed care enrollment penetration were also concerned about the AMRP process because the remaining FFS populations in their State often reside in long-term care facilities or require only specialized care that is carved out from managed care, but long-term care and specialized care services were not required to be analyzed under the AMRP process. We have also heard concerns from other interested parties, including medical associations and non-profit organizations, that the 2015 final rule with comment period afforded States too much discretion in developing access measures which could lead to ineffective monitoring and enforcement as well as challenges comparing access across States. One commenter was concerned that States had too much discretion in "...setting standards and access measures..." and "...whether they have met their chosen standards" as this process relies on self-regulation rather than "an independent, objective third party as the primary arbiter of a State's compliance..."106 Another commenter stated that "CMS should designate a limited and standardized set of data measures that would be collected rather than leaving the decision of which data measures to use to State discretion" as this would "enable the development of key,

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¹⁰³ 76 FR 26341.

¹⁰⁴ 80 FR 67576 at 67583-67584.

¹⁰⁵ 81 FR 21479 at 21479.

¹⁰⁶ American Medical Association, Comment Letter on 2015 Final Rule with Comment Period (January 4, 2016), https://www.regulations.gov/comment/CMS-2011-0062-0328.

valid, and uniform measures; more effective monitoring and enforcement; and will ensure comparability of objective measures across the States."107 At the time of publication of the 2011 proposed rule and 2015 final rule with comment period, we believed that a uniform approach to meeting the statutory requirement under section 1902(a)(30)(A) of the Act, including setting standardized access to care data measures, could prove difficult given then-current limitations on data, local variations in service delivery, beneficiary needs, and provider practice roles. 108,109

Separately, the Supreme Court, in Armstrong v. Exceptional Child Center, Inc., 135 S. Ct. 1378 (2015), ruled that Medicaid providers and beneficiaries do not have a private right of action to challenge Medicaid payment rates in Federal courts. This decision means provider and beneficiary legal challenges are unavailable in Federal court to supplement our oversight as a means of ensuring compliance with section 1902(a)(30)(A) of the Act. The Armstrong decision also underscored HHS' and CMS' unique responsibility for resolving issues concerning the interpretation and implementation of section 1902(a)(30)(A) of the Act. By concluding that the responsible Federal administrative agency is better suited than Federal courts to make determinations regarding the sufficiency of Medicaid payment rates, the Supreme Court's Armstrong decision placed added importance on CMS' administrative review of SPAs proposing to reduce or restructure FFS payment rates. Accordingly, the 2015 final rule with comment period was an effort to establish a more robust oversight and enforcement strategy with respect to section 1902(a)(30)(A) of the Act.

In consideration of State agencies' and other interested parties' feedback on the AMRP process, as well as CMS' obligation to ensure continued compliance with section 1902(a)(30)(A) of the Act, we propose to update the requirements in § 447.203. We propose to rescind and replace the AMRP requirements currently in § 447.203(b)(1) through (8) with a streamlined and standardized process, described in proposed § 447.203(b) and (c). This proposed change is

¹⁰⁷ American Association of Retired Persons, Comment Letter on 2011 Propose Rule (July 5, 2011), https://www.regulations.gov/comment/CMS-2011-0062-0121.

¹⁰⁸ 76 FR 26341 at 26349.

^{109 80} FR 67576 at 67577, 67579, 67590.

informed by a center-wide review of our policy and processes regarding access to care for all facets of the Medicaid program. The 2015 final rule with comment period acknowledged our need to better understand FFS rate actions and their potential impact on State programs, and the requirements we finalized require a considerable amount of data from States. To ensure States were meeting the statutory requirement under section 1902(a)(30)(A) of the Act, the AMRP process was originally intended to establish a transparent data-driven process for States to measure the current status of access to services within the State and utilize this process for monitoring access when proposing rate reductions and restructurings. 110 As the rule took effect and as we reviewed State's AMRPs, we found that some rate reductions and restructurings had much smaller impacts than others. The 2017 SMDL reflected the experience that certain payment rate changes would not likely result in diminished access to care and do not require the substantial review of access data that generally is required under the 2015 final rule with comment period. Since publication of the 2019 CMCS Informational Bulletin stating the agency's intention to establish a new access strategy, we have developed this proposal for a new process that considers the lessons learned under the AMRP process, and emphasizes transparency and data analysis, with specific proposed requirements varying depending on the State's current payment levels relative to Medicare, the magnitude of the proposed rate reduction or restructuring, and any access to care concerns raised to State Medicaid agency by interested parties. With these proposed provisions, we aim to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act (and our obligation to oversee State compliance with the same).

1. Fully Fee-For-Service States

We are seeking comment on whether additional access standards for States with a fully
FFS delivery system may be appropriate. Because the timeliness standards of the proposed
Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality

110 80 FR 67576 at 67577.

proposed rule (Managed Care proposed rule) at § 438.68 would not apply to any care delivery in such States, we are considering whether a narrow application of timeliness standards to fully FFS States that closely mirrors the proposed appointment wait time standards, secret shopper survey requirements, and publication requirements (as applied to outpatient mental health and substance use disorder, adult and pediatric; primary care, adult and pediatric; obstetrics and gynecology; and an additional type of service determined by the State) in that rule might be appropriate. Given that timeliness standards would apply directly to States, we also seek comment on a potentially appropriate method for CMS to collect data demonstrating that States meet the established standards at least 90 percent of the time.

2. Payment Rate Transparency (§ 447.203(b))

We propose to rescind § 447.203(b) in its entirety and replace it with new requirements to ensure FFS Medicaid payment rate adequacy, including a new process to promote payment rate transparency. This new proposed process would require States to publish their FFS Medicaid payment rates in a clearly accessible, public location on the State's website, as described later in this section. Then, for certain services, States would be required to conduct a comparative payment rate analysis between the States' Medicaid payment rates and Medicare rates, or provide a payment rate disclosure for certain HCBS that would permit CMS to develop and publish HCBS payment benchmark data.

In paragraph (b)(1), we propose to require the State agency to publish all Medicaid FFS payment rates on a website developed and maintained by the single State agency that is accessible to the general public. We propose that published Medicaid FFS payment rates would include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. We also propose to require that the website be easily reached from a hyperlink easily reached from a hyperlink on the State Medicaid agency's website.

Within this payment rate publication, we propose that FFS Medicaid payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. We also propose that, if the rates vary, the State must separately identify the Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.

Longstanding legal requirements to provide effective communication with individuals with disabilities and the obligation to take reasonable steps to provide meaningful access to individuals with limited English proficiency also apply to the State's website containing Medicaid FFS payment rate information. Under Title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act, section 1557 of the Affordable Care Act, and implementing regulations, qualified individuals with disabilities may not be excluded from participation in, or denied the benefits of any programs or activities of the covered entity, or otherwise be subjected to discrimination by any covered entity, on the basis of disability, and programs must be accessible to people with disabilities.¹¹¹ Individuals with disabilities are entitled to communication that is as effective as communication for people without disabilities, including through the provision of auxiliary aids and services. 112 Section 1557 of the Affordable Care Act requires recipients of Federal financial assistance, including State Medicaid programs, to take reasonable steps to provide meaningful access to their programs or activities for individuals with limited English proficiency, and requires the provision of interpreting services and translations when it is a reasonable step to provide meaningful access. 113

We propose that for States that pay varying Medicaid FFS payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, those States would

¹¹¹²⁹ U.S.C. 794; 42 U.S.C. 18116(a); 42 U.S.C. 12132; 28 CFR. 35.130(a); 45 CFR 84.4 (a); 45 CFR 92.2(b).

¹¹²28 CFR 35.160; 45 CFR 92.102; see also 45 CFR 84.52(d).

¹¹³ 45 CFR 92.101; see also https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/guidance-federal-financial-assistance-title-vi/index.html.

need to separately identify their Medicaid FFS payment rates in the payment rate transparency publication by each grouping or multiple groupings, when applicable to a State's program. In the event rates vary according to these factors, as later discussed in this proposed rule, our intent is that a member of the public be readily able to determine the payment amount that would be made, accounting for all relevant circumstances. For example, a State that varies their Medicaid FFS payment rates by population may pay for a service identified by code 99202 when provided to a child at a rate of \$110.00 and when provided to an adult at a rate of \$80.00. Because the Medicaid FFS payment rates vary based on population, both of these Medicaid FFS payment rates would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication. As another example, a State that varies their Medicaid FFS payment rates by provider type may pay for 99202 when delivered by a physician at a rate of \$50.00, and when delivered by a nurse practitioner or physician assistant at a rate of \$45.00.

We are aware that some State plans include language that non-physician practitioners (NPPs), such as a nurse practitioner or physician assistant, are paid a percentage of the State's fee schedule rate. Because the Medicaid FFS payment rates vary by provider type, both of the Medicaid FFS payment rates in both situations (fee schedule rates of \$50.00 and \$45.00) would need to be separately identified as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication, regardless of whether the State has individually specified each amount certain in its approved payment schedule or has State plan language specifying the nurse practitioner or physician assistant rate as a percentage of the physician rate. Additionally, for example, a State that varies their Medicaid FFS payment rates by geographical location may pay for 99202 delivered in a rural area at a rate of \$70, in an urban or non-rural area as a rate of \$60, and in a major metropolitan area as a rate of \$50. We are also aware that States may vary their Medicaid FFS payment rates by geographical location by zip code, by metropolitan or micropolitan areas, or other geographical location breakdowns determined by the State. Because

the Medicaid FFS payment rates vary based on geographical location, all Medicaid FFS payment rates based on geographical location would need to be included separately as Medicaid FFS payment rates for 99202 in the State's payment rate transparency publication.

For a State that varies its Medicaid FFS payment rates by any combination of these groupings, then the payment rate transparency publication would be required to reflect these multiple groupings. For example, the State would be required to separately identify the rate for a physician billing 99202 provided to a child in a rural area, the rate for a nurse practitioner billing 99202 provided to a child in a rural area, the rate for a physician billing 99202 provided to an adult in a rural area, the rate for a nurse practitioner billing 99202 provided to an adult in a rural area, the rate for a physician billing 99202 provided to a child in an urban area, the rate for a nurse practitioner billing 99202 provided to a child in an urban area, and so on. This information would be required to be presented clearly so that a member of the public can readily determine the payment rate for a service that would be paid for each grouping or combination of groupings (population (pediatric and adult), provider type, and geographical location), as applicable. We acknowledge that States may also pay a single Statewide rate regardless of population (pediatric and adult), provider type, and geographical location, and as such would only need to list the single Statewide rate in their payment rate transparency publication.

We acknowledge that there may be additional burden associated with our proposal that the payment rate transparency publication include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' Medicaid FFS payment rates vary based on these groupings. Despite the additional burden, we believe that the additional level of granularity in the payment rate transparency publication is important for ensuring compliance with section 1902(a)(30)(A) of the Act, given State Medicaid programs rely on multiple provider types to deliver similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each area of each State.

We further propose that Medicaid FFS payment rates published under the proposed payment rate transparency requirement would only include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a FFS delivery system. To ensure maximum transparency in the case of a bundled fee schedule payment rate or rate determined by a similar payment methodology where a single payment rate is used to pay for multiple services, we propose that the State must identify each constituent service included in the bundled fee schedule payment rate or rate determined by a similar payment methodology. We also propose that the State must identify how much of the bundled fee schedule payment rate or rate determined by a similar payment methodology is allocated to each constituent service under the State's payment methodology. For example, if a State's fee schedule lists a bundled fee schedule rate that pays for day treatment under the rehabilitation benefit and the following services are included in the day treatment bundle: community based psychiatric rehabilitation and support services, individual therapy, and group therapy, then the State would need to identify services community based psychiatric rehabilitation and support services, individual therapy, and group therapy separately and each portion of the bundled fee schedule payment rate for day treatment that is allocated to community based psychiatric rehabilitation and support services, individual therapy, and group therapy. Proposing to require States identify the portion of the bundled fee is allocable to each constituent service included in the bundled fee schedule payment rate would add an additional level of granularity to the payment rate transparency publication that continues to enable a member of the public to readily be able to determine the payment amount that would be made for a service, accounting for all relevant circumstances, including the payment rates for each constituent service within a bundle and as a standalone service. We also propose to require that the website be easily reached from a hyperlink to ensure transparency of payment rate information is available to beneficiaries, providers, CMS, and other interested parties.

We propose the initial publication of Medicaid FFS payment rates would occur no later than January 1, 2026, and include approved Medicaid FFS payment rates in effect as of that date, January 1, 2026. We propose this timeframe to provide States with at least 2 years from the possible effective date of the final rule, if this proposal is finalized, to comply with the payment rate transparency requirement. The proposed timeframe would initially set a consistent baseline for all States to first publish their payment rate transparency information and then set a clear schedule for States to update their payment rates based on the cadence of the individual States' payment rate changes.

The same initial publication due date for all States to publish their payment rates as of January 1, 2026, would promote comparability between States' payment rate transparency publications. Once States would begin making updates to their payment rate transparency publication, there would be a clear distinction between State payment rates that have recently updated their payment rates and State payment rates that have long maintained the same payment rates. For example, two States initially publish their payment rates for 99202 at \$50; however, one State annually increases their payment rate by 5 percent over the next 2 years and would update their payment rate transparency publication in 2027 with a payment rate of \$52.50, then in 2028 with a payment rate of \$55.13, while the other States' payment rate for the same service remains at \$50 in 2027 and 2028. The transparency of a State's recent payment rates including the date the payment rates were last updated on the State Medicaid agency's website, as discussed later, as well as the ability to compare payment rates between States on accessible and easily reachable State-maintained websites, highlights how the proposed payment rate transparency would help to ensure that Medicaid payment rate information is available to beneficiaries, providers, CMS, and other interested parties for the purposes of assessing access to care issues to better ensure compliance with section 1902(a)(30)(A) of the Act.

We also propose that the initial publication include approved Medicaid FFS payment rates in effect as of January 1, 2026. We propose this language to narrow the scope of the

publication to CMS-approved payment rates and methodologies, thereby excluding any rate changes for which a SPA or similar amendment request is pending CMS review or approval.

SPAs are submitted throughout the year, can include retroactive effective dates, and are subject to a CMS review period that varies in duration. 114,115

As discussed later in this proposed rule regarding paragraph (b)(2) and(b)(3), States are encouraged to use the proposed payment rate transparency publication as a source of Medicaid payment rate data for compliance with the paragraph (b)(3)(i)(B) proposed comparative payment rate analysis and paragraph (b)(3)(ii)(B) proposed payment rate disclosure requirements. However, we note that the comparative payment rate analysis and payment rate disclosure requirements impose a one-year lag on the date when rates are effective. We include a more indepth discussion of the timeframes for publication of the comparative payment rate analysis and payment rate disclosure in paragraph (b)(4) later in this proposed rule, where we note that the 1year shift in timeframe is necessitated by the timing of when Medicare publishes their payment rates in November and the rates taking effect on January 1, leaving insufficient time for CMS to publish the code list for States to use for the comparative payment rate analysis and for States develop and publish their comparative payment rate analysis and payment rate disclosure by January 1. We note that the ongoing payment transparency publication requirements will allow the public to view readily available, current Medicaid payment rates at all times, even if slightly older Medicaid payment rate information must be used for comparative payment rate analyses due to the cadence of Medicare payment rate changes as well as the payment rate disclosure. We are cognizant that the payment rate disclosure does not depend on the availability of Medicare payment rates, however, we are proposing to provide States with the same amount of time to

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¹¹⁴ In accordance with 42 CFR 430.20, an approved SPA can be effective no earlier than the first day of the calendar quarter in which an approvable amendment is submitted. For example, a SPA submitted on September 30th can be retroactively effective to Inly 1st

¹¹⁵ In accordance with 42 CFR 430.16, a SPA will be considered approved unless CMS, within 90 days after submission, requests additional information or disapproves the SPA. When additional information is requested by CMS and the State has respond to the request, CMS will then have another 90 days to either approve, disapprove, and request the State withdraw the SPA or the State's response to the request for additional information. This review period includes two 90-day review periods plus additional time when CMS has requested additional information which can result is a wide variety of approval timeframes.

comply with both of the proposed comparative payment rate analysis and payment rate disclosure requirements.

If this proposal is finalized at a time that does not allow for States to have a period of at least 2 years between the effective date of the final rule and the proposed January 1, 2026, due date for the initial publication of Medicaid FFS payment rates, then we would propose an alternative date of July 1, 2026, for the initial publication of Medicaid FFS payment rates and for the initial publication to include approved Medicaid FFS payment rates as of that date, July 1, 2026. This shift would allow more time for States to comply with the payment rate transparency requirements. We acknowledge that the date of the initial payment rate transparency publication is subject to change based on the final rule publication schedule and effective date, if this rule is finalized. If further adjustment is necessary beyond the July 1, 2026, timeframe to allow adequate time for States to comply with the payment rate transparency requirements, then we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate, to allow for approximately 2 years between the effective date of the final rule and the initial required payment rate transparency publication.

We propose to require the that the single State agency include the date the payment rates were last updated on the State Medicaid agency's website. We also propose to require that the single State agency ensure that Medicaid FFS payment rates are kept current where any necessary updates to the State fee schedules made no later than 1 month following the date of CMS approval of the SPA, section 1915(c) HCBS waiver, or similar amendment revising the provider payment rate or methodology. Finally, in paragraph (b)(1), we propose that, in the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State would be required to update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate. This provision is intended to capture Medicaid FFS payment rate changes that occur because of previously approved SPAs containing payment rate methodologies. For example, if a State sets

their Medicaid payment rates for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) at a percentage of the most recent Medicare fee schedule rate, then the State's payment rate would change when Medicare adopts a new fee schedule rate through the quarterly publications of the Medicare DMEPOS fee schedule, unless otherwise specified in the approved State plan methodology that the State implements a specific quarterly publication, for example, the most recent April Medicare DMEPOS fee schedule. Therefore, the State's Medicaid FFS payment rate automatically updates when Medicare publishes a new fee schedule, without the submission of a SPA because the State's methodology pays a percentage of the most recent State plan specified Medicare fee schedule rate. In this example, the State would need to update its Medicaid FFS payment rates in the payment rate transparency publication no later than 1 month after the effective date of the most recent update to the Medicare fee schedule payment rate made applicable under the approved State plan payment methodology.

While there is no current Federal requirement for States to consistently publish their rates in a publicly accessible manner, we are aware that most States already publish at least some of their payments through FFS rate schedules on State agency websites. Currently, rate information may not be easily obtained from each State's website in its current publication form, making it difficult to understand the amounts that States pay providers for items and services furnished to Medicaid beneficiaries and to compare Medicaid payment rates to other health care payer rates or across States. However, through this proposal we seek to ensure all States do so in a format that is publicly accessible and where all Medicaid FFS payment rates can be easily located and understood. The new transparency requirements under this proposed rule would help to ensure that interested parties have access to updated payment rate schedules and could conduct analyses that would provide insights into how State Medicaid payment rates compare to, for example, Medicare payment rates and other State Medicaid payment rates. The proposal intends to help ensure that payments are transparent and clearly understandable to beneficiaries, providers, CMS, and other interested parties. We are seeking public comment on the proposed requirement

for States to publish their Medicaid FFS payment rates for all services, the proposed structure for Medicaid FFS payment rate transparency publication on the State's website, and the timing of the publication of and updates to the State's Medicaid FFS payment rates for the proposed payment rate transparency requirements in § 447.203(b)(1).

In paragraph (b)(2), we propose to require States to develop and publish a comparative payment rate analysis of Medicaid payment rates for certain specified services, and a payment rate disclosure for certain HCBS. In paragraph (b)(2) we specify the categories of services that States would be required to include in a comparative payment rate analysis and payment rate disclosure of Medicaid payment rates. Specifically, we are proposing that for each of the categories of services in paragraphs (b)(2)(i) through (iii), each State agency would be required to develop and publish a comparative payment rate analysis of Medicaid payment rates as specified in proposed § 447.203(b)(3). We also propose that for each of the categories of services in paragraph (b)(2)(iv), each State agency would be required to develop and publish a payment rate disclosure of Medicaid payment rates as specified in proposed § 447.203(b)(3). We propose for both the comparative payment rate analysis and payment rate disclosure that, if the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The categories of services listed in paragraph (b)(2) include: primary care services; obstetrical and gynecological services; outpatient behavioral health services; and personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.

In paragraph (b)(2), we propose to require States separately identify the payment rates in the comparative payment rate analysis and payment rate disclosure, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. These proposed breakdowns of the Medicaid payment rates, similar to how we propose payment rates would be broken down in the payment rate transparency disclosures under proposed

§ 447.203(b)(1), would apply to all proposed categories of services listed in paragraph (b)(2): primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

We acknowledge that not all States pay varied payment rates by population (pediatric and adult), provider type, and geographical location, which is why we have included language "if the rates vary" and "as applicable" in the proposed regulatory text. This language is included in the proposed regulatory text to ensure the comparative payment rate analysis and payment rate disclosure captures all Medicaid payment rates, including when States pay varied payment rates by population (pediatric and adult), provider type, and geographical location. We also included proposed regulatory text for the payment rate disclosure that ensures the average hourly payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency are separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary, as later discussed in connection with proposed § 447.203(b)(3)(ii). For States that do not pay varied payment rates by population (pediatric and adult), provider type, and geographical location and pay a single Statewide payment rate for a single service, then the comparative payment rate analysis and payment rate disclosure would only need to include the State's single Statewide payment rate.

We propose to include a breakdown of Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, on the Medicaid side of the comparative payment rate analysis in paragraph (b)(2) to align with the proposed payment rate transparency provision, to account for State Medicaid programs that pay variable Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, and to help ensure the State's comparative payment rate analyses accurately align with Medicare. Following the initial year that the provisions proposed in this rule would be in effect, these proposed provisions would align with and build on the payment rate transparency requirements

described in § 447.203(b)(1), because States could source the codes and their corresponding Medicaid payment rates that the State already would publish to meet the payment rate transparency requirements.

These proposed provisions are also intended to help ensure that the State's comparative payment rate analysis contains the highest level of granularity in each proposed aspect by considering and accounting for any variation in Medicaid payment rates by population (pediatric and adult), provider type, and geographical location, as currently required in the AMRP process under current § 447.203(b)(1)(iv) and (v), and (b)(3). Additionally, Medicare varies payment rates for certain NPPs (nurse practitioners, physician assistants, and clinical nurse specialists) by paying them 85 percent of the full Medicare physician fee schedule amount and varies their payment rates by geographical location through calculated adjustments to the pricing amounts to reflect the variation in practice costs from one geographical location to another; therefore, the comparative payment rate analysis accounting for these payment rate variations is crucial to ensuring the Medicaid FFS payment rates accurately align with FFS Medicare Physician Fee Schedule (PFS) rates. 116 As discussed later in this proposed rule, Medicare payment variations for provider type and geographical location would be directly compared with State Medicaid payment rates that also apply the same payment variations, in addition to payment variation by population (pediatric and adult) which is unique to Medicaid, yet an important payment variation to take into consideration when striving for transparency of Medicaid payment rates. For States that do not pay varied payment rates by population (pediatric and adult), provider type, or geographical location and pay a single Statewide payment rate for a single service, Medicare payment variations for provider type and geographical location would be considered by calculating a Statewide average of Medicare PFS rates which is later discussed in this proposed rule.

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¹¹⁶ https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_Physician_FINAL_SEC.pdf.

Similar to the payment rate transparency publication, we acknowledge that there may be additional burden associated with our proposal that the payment rate transparency publication and the comparative payment rate analysis include a payment rate breakdown by population (pediatric and adult), provider type, and geographical location, as applicable, when States' payment rates vary based on these groupings. However, we believe that any approach to requiring a comparative payment rate analysis would involve some level of burden that is greater for States that choose to employ these payment rate differentials, since any comparison methodology would need to take account – through a separate comparison, weighted average, or other mathematically reasonable approach – of all rates paid under the Medicaid program for a given service. In all events, we believe this proposal would create an additional level granularity in the analysis that is important for ensuring compliance with section 1902(a)(30)(A) of the Act. Multiple types of providers, for example, physicians, physician assistants, and nurse practitioners, are delivering similar services to Medicaid beneficiaries of all ages, across multiple Medicaid benefit categories, throughout each State. Section 1902(a)(30)(A) states "...that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area," and we believe that having sufficient access to a variety of provider types is important to ensuring access for Medicaid beneficiaries meets this statutory standard. For example, a targeted payment rate reduction to nurse practitioners, who are often paid less than 100 percent of the State's physician fee schedule rate, could have a negative impact on access to care for services provided by nurse practitioners, but this reduction would not directly impact physicians or their willingness to participate in Medicaid and furnish services to beneficiaries. By proposing that the comparative payment rate analysis include a breakdown by provider type, where States distinguish payment rates for a service by provider type, the analysis would capture this payment rate variation among providers of the same services and provide us with a granular level of information to aid in

determining if access to care is sufficient, particularly in cases where beneficiaries depend to a large extent on the particular provider type(s) that would be affected by the proposed rate change for the covered service(s).

We identified payment rate variation by population (pediatric and adult), provider type, and geographical location as the most commonly applied adjustments to payment rates that overlap between FFS Medicaid and Medicare and could be readily broken down into separately identified payment rates for comparison in the comparative payment rate analysis. For transparency purposes and to help to ensure the comparative payment rate analysis is conducted at a granular level of analysis, we believe it is important for the State to separately identify their rates, if the rates vary, by population (pediatric and adult), provider type, and geographical location, as applicable. We are seeking public comments on the proposal to require the comparative payment rate analysis includes, if the rates vary, separate identification of payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the comparative payment rate analysis in proposed § 447.203(b)(2).

We acknowledge that States may apply additional payment adjustments or factors, for example, the Consumer Price Index, Medicare Economic Index, or State-determined inflationary factors or budget neutrality factors, to their Medicaid payment rates other than population (pediatric and adult), provider type, and geographical location identified in this proposed rule. We would expect any other additional payment adjustments and factors to already be included in the State's published Medicaid fee schedule rate or calculable from the State plan because § 430.10 requires the State plan to be a "comprehensive written statement...contain[ing] all information necessary for CMS to determine whether the plan can be approved to serve as a basis for...FFP..." Therefore, for States paying for services with a fee schedule payment rate, the Medicaid fee schedule is the sole source of information for providers to locate their final payment rate for Medicaid services provide to Medicaid beneficiaries under a FFS delivery system. For States with a rate-setting methodology where the approved State plan describes how

rates are set based upon a fee schedule (for example, payment for NPPs are set a percentage of a certain published Medicaid fee schedule), the Medicaid fee schedule would again be the source of information for providers to identify the relevant starting payment rate and apply the rate-setting methodology described in the State plan to ascertain their Medicaid payment. We are also seeking public comment on any additional types of payment adjustments or factors States make to their Medicaid payment rates as listed on their State fee schedules that should be identified in the comparative payment rate analysis that we have not already discussed in § 447.203(b)(i)(B) of this proposed rule, and how the inclusion of any such additional adjustments or factors should be considered in the development of the Medicare PFS rate to compare Medicaid payment rates to, as later described in § 447.203(b)(3)(i)(C), of this proposed rule.

In paragraphs (b)(2)(i) through (iv), we propose that primary care services, obstetrical and gynecological services, and outpatient behavioral health services would be subject to a comparative payment rate analysis of Medicaid payment rates and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency would be subject to a payment rate disclosure of Medicaid payment rates. We begin with a discussion about the importance of primary care services, obstetrical and gynecological services, and outpatient behavioral health services as proposed in § 447.203(b)(2)(i) through (iii), and the reason for their inclusion in this proposed requirement. Then, we will discuss the importance and justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as proposed in § 447.203(b)(2)(iv).

In § 447.203(b)(2)(i) through (iii), we propose to require primary care services, obstetrical and gynecological services, and outpatient behavioral health services be included in the comparative payment rate analysis, because we believe that these categories of services are

 $^{^{117} \} https://www.medicaid.gov/state-resource-center/downloads/spa-and-1915-waiver-processing/fed-req-pymt-methodologies.docx.$

critical preventive, routine, and acute medical services in and of themselves, and that they often serve as gateways to access to other needed medical services, including specialist services, laboratory and x-ray services, prescription drugs, and other mandatory and optional Medicaid benefits that States cover. Including these categories of services in the comparative payment rate analysis would require States to closely examine their Medicaid FFS payment rates to comply with section 1902(a)(30)(A) of the Act. As described in the recent key findings from public comments on the February 2022 RFI that we published, payment rates are a key driver of provider participation in the Medicaid program. By proposing that States compare their Medicaid payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services to Medicare payment rates, States would be required to analyze if and how their payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

As discussed later in this section, we believe that Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to a beneficiary because Medicare delivers services through a FFS delivery system across all geographical regions of the US and historically, the vast majority of physicians accept new Medicare patients, with extremely low rates of physicians opting out of the Medicare program, suggesting that Medicare's payment rates are generally consistent with a high level of physician willingness to accept new Medicare patients.¹¹⁹

Additionally, Medicare payment rates are publicly published in an accessible and consistent

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¹¹⁸ Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.

¹¹⁹ Physicians and practitioners who do not wish to enroll in the Medicare program may "opt-out" of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states, that neither one can receive payment from Medicare for the services that were performed. See https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.

format by CMS making Medicare payment rates an available and reliable comparison point for States, rather than private payer data which typically is considered proprietary information and not generally available to the public. Therefore, the proposed requirement that States develop and publish a comparative payment rate analysis would enable States, CMS, and other interested parties to closely examine the relationship between State Medicaid FFS payment rates and those paid by Medicare. This analysis would continually help States to ensure that their Medicaid payment rates are set at a level that is likely sufficient to meet the statutory access standard under 1902(a)(30)(A) of the Act that payments by enlisting enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. We believe that the comparative payment rate analysis would provide States, CMS, and other interested parties with clear and concise information for identifying when there is a potential access to care issue, such as Medicaid payment rates not keeping pace with changes in corresponding Medicare rates and decreases in claims volume and beneficiary utilization of services. As discussed later in this section, numerous studies have found a relationship between Medicaid payment rates and provider participation in the Medicaid program and, given the statutory standard of ensuring access for Medicaid beneficiaries, a comparison of Medicaid payment rates to other payer rates, particularly Medicare payment rates as justified later in this rule, is an important barometer of whether State payment rates and policies are sufficient for meeting the statutory access standard under section 1902(a)(30)(A) of the Act.

We propose to focus on these particular services because they are critical medical services and of great importance to overall beneficiary health. Beginning with primary care, these services provide access to preventative services and facilitate the development of crucial doctor-patient relationships. Primary care providers often deliver preventative health care services, including immunizations, screenings for common chronic and infectious diseases and cancers, clinical and behavioral interventions to manage chronic disease and reduce associated

risks, and counseling to support healthy living and self-management of chronic diseases; Medicaid coverage of preventative health care services promotes disease prevention which is critical to helping people live longer, healthier lives. 120 Accessing primary care services can often result in beneficiaries receiving referrals or recommendations to schedule an appointment with physician specialists, such as gastroenterologists or neurologists, that they would not be able to obtain without the referral or recommendation by the primary care physician. Additionally, primary care physicians provide beneficiaries with orders for laboratory and x-ray services as well as prescriptions for necessary medications that a beneficiary would not be able to access without the primary care physician. Research over the last century has shown that the impact of the doctor-patient relationship on patient's health care experience, health outcomes, and health care costs exists¹²¹ and more recent studies have shown that the quality of the physician-patient relationship is positively associated with functional health among patients. 122 Another study found that higher primary care payment rates reduced mental illness and substance use disorders among non-elderly adult Medicaid enrollees, suggesting that positive spillover from increasing primary care rates also positively impacted behavioral health outcomes. 123 Lastly, research has shown that a reduction in barriers to accessing primary care services has been associated with helping reduce health disparities and the risk of poor health outcomes. 124,125 These examples illustrate how crucial access to primary care services is for overall beneficiary health and to enable access to other medical services. We are seeking public comment on primary care services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i).

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¹²⁰ https://www.medicaid.gov/medicaid/benefits/prevention/index.html.

¹²¹ Cockerham, W. C. (2021). The Wiley Blackwell Companion to Medical Sociology (1st ed.). John Wiley & Sons.

¹²² Olaisen, R. H., Schluchter, M. D., Flocke, S. A., Smyth, K. A., Koroukian, S. M., & Stange, K. C. (2020). Assessing the longitudinal impact of physician-patient relationship on Functional Health. *The Annals of Family Medicine*, 18(5), 422–429. https://doi.org/10.1370/afm.2554.

¹²³ Maclean, Johanna Catherine, McCleallan, Chandler, Pesko, Michael F., and Polsky, Daniel. (2023). Medicaid reimbursement rates for primary care services and behavioral health outcomes. Health economics, 1-37. https://doi.org/10.1002/hec.4646.

¹²⁴ Starfield, B., Shi, L., & Macinko, J. (2005). Contribution of primary care to health systems and health. The Milbank quarterly, 83(3), 457–502. https://doi.org/10.1111/j.1468-0009.2005.00409.x.

¹²⁵ https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/access-primary-care.

Similar to primary care services, both obstetrical and gynecological services and outpatient behavioral health services provide access to preventative and screening services unique to each respective field. A well-woman visit to an obstetrician-gynecologist often provides access to screenings for cervical and breast cancer; screenings for Rh(D) incompatibility, syphilis infection, and hepatitis B virus infection in pregnant persons; monitoring for healthy weight and weight gain in pregnancy; immunization against the human papillomavirus infection; and perinatal depression screenings among other recommended preventive services. 126,127 Behavioral health care promotes mental health, resilience, and wellbeing; the treatment of mental and substance use disorders; and the support of those who experience and/or are in recovery from these conditions, along with their families and communities. Outpatient behavioral health services can overlap with preventative primary care and obstetrical and gynecological services, for example screening for depression in adults and perinatal depression screenings, but also provide unique preventative and screening services such as screenings for unhealthy alcohol use in adolescents and adults, anxiety in children and adolescents, and eating disorders in adolescents and adults, among other recommended preventive services. 128

The U.S. is simultaneously experiencing a maternal health crisis and mental health crisis, putting providers of obstetrical and gynecological and outpatient behavioral health services, respectively, at the forefront. According to MACPAC, "Medicaid plays a key role in providing maternity-related services for pregnant women, paying for slightly less than half of all births nationally in 2018." Given Medicaid's significant role in maternal health during a time

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¹²⁶ Rh(D) incompatibility is a preventable pregnancy compilation where a woman who is Rh negative is carrying a fetus that is Rh positive (Rh factor is a protein that can be found on the surface of red blood cells). When the blood of an Rh-positive fetus gets into the bloodstream of an Rh-negative woman, her body will recognize that the Rh-positive blood is not hers. Her body will try to destroy it by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells. This can lead to serious health problems, even death, for a fetus or a newborn. Prevention of Rh(D) incompatibility screening for Rh negative early in pregnancy (or before pregnancy) and, if needed, giving you a medication to prevent antibodies from forming.

¹²⁷ https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/10/well-woman-visit.

¹²⁸ https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P.

¹²⁹ https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf.

 $^{^{130}\} https://www.whitehouse.gov/briefing-room/statements-releases/2022/05/31/fact-sheet-biden-harris-administration-highlights-strategy-to-address-the-national-mental-health-crisis/.$

¹³¹ https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf.

when maternal mortality rates in the United States continue to worsen and the racial disparities among mothers continues to widen, ^{132,133} accessing obstetrical and gynecological care, including care before, during, and after pregnancy is crucial to positive maternal and infant outcomes. ¹³⁴ We are seeking public comment on obstetrical and gynecological services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(ii).

Improving access to behavioral health services is a critical, national issue facing all payors, particularly for Medicaid which plays a crucial role in mental health care access as the single largest payer of services and has a growing role in payment for substance use disorder services, in part due to Medicaid expansion and various efforts by Congress to improve access to mental health and substance use disorder services. Several studies have found an association between reducing the uninsured rate through increased Medicaid enrollment and improved and expanded access to critically needed behavioral health services. Numerous studies have found positive outcomes associated with Medicaid expansion: increases in the insured rate and access to care and medications for adults with depression, increases in coverage rates and a greater likelihood of being diagnosed with a mental health condition as well as the use of prescription medications for a mental health condition for college students from disadvantaged backgrounds, and a decrease in delayed or forgone necessary care in a nationally representative sample of non-elderly adults with serious psychological distress. While individuals who are covered by Medicaid have better access to behavioral health services

¹³² https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2020/maternal-mortality-rates-2020.htm.

¹³³ https://www.nytimes.com/2022/02/23/health/maternal-deaths-pandemic.html?smid=url-share.

¹³⁴ https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Carein-Rural-Communities.pdf.

 $^{^{135}\} https://www.medicaid.gov/medicaid/access-care/downloads/coverage-and-behavioral-health-data-spotlight.pdf.$

¹³⁶ https://www.medicaid.gov/medicaid/benefits/behavioral-health-services/index.html.

¹³⁷ https://www.cbpp.org/research/health/to-improve-behavioral-health-start-by-closing-the-medicaid-coverage-gap.

¹³⁸ Cowan, Benjamin W. & Hao, Zhuang. (2021). Medicaid expansion and the mental health of college students. Health economics, 30(6), 1306-1327. https://www.nber.org/system/files/working_papers/w27306/w27306.pdf.

¹³⁹ Novak, P., Anderson, A. C., & Chen, J. (2018). Changes in Health Insurance Coverage and Barriers to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act. Administration and policy in mental health, 45(6), 924–932. https://doi.org/10.1007/s10488-018-0875-9.

compared to people who are uninsured, some coverage gaps remain in access to behavioral health care for many people, including those with Medicaid.

Some of the barriers to accessing behavioral health treatment in Medicaid reflect larger system-wide access problems: overall shortage of behavioral health providers in the United States and relatively small number of psychiatrists who accept any form of insurance or participate in health coverage programs. ¹⁴⁰ Particularly for outpatient behavioral health services for Medicaid beneficiaries, one reason physicians are unwilling to accept Medicaid patients is because of low Medicaid payment rates.¹⁴¹ One study found evidence of low Medicaid payment rates by examining outpatient Medicaid claims data from 2014 in 11 States with a primary behavioral health diagnosis and an evaluation and management (E/M) procedure code of 99213 (Established patient office visit, 20-29 minutes) or 99214 (Established patient office visit, 30-39 minutes) and found that psychiatrists in nine States were paid less, on average, than primary care physicians. 142 These pieces of research and data about the importance of outpatient behavioral health services and the existing challenges beneficiaries face in trying to access outpatient behavioral health services underscore how crucial access to outpatient behavioral health services is, and that adequate Medicaid payment rates for these services is likely to be an important driver of access for beneficiaries. We are seeking public comment on outpatient behavioral health services as one of the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(iii).

In § 447.203(b)(2)(iv), we propose to require personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in the payment rate disclosure requirements proposed in § 447.203(b)(3)(ii). We are cognizant that many HCBS providers nationwide are facing workforce shortages and high staff turnover that have been exacerbated by the COVID-19 pandemic, and these issues and related difficulty

140 https://www.kff.org/medicaid/issue-brief/medicaids-role-in-financing-behavioral-health-services-for-low-income-individuals/ ¹⁴¹ https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/.

¹⁴² Mark, Tami L., Parish, William, Zarkin, Gary A., and Weber, Ellen. (2020). Comparison of Medicaid Reimbursements for Psychiatrists and Primary Care Physicians. Psychiatry services 71(9), 947-950. https://doi.org/10.1176/appi.ps.202000062.

accessing HCBS can lead to higher rates of costly, institutional stays for beneficiaries. 143 As with any covered service, the supply of HCBS providers has a direct and immediate impact on beneficiaries' ability to access high quality HCBS, therefore, we included special considerations for LTSS, specifically HCBS, through two proposed provisions in § 447.203. The first provision in proposed paragraph (b)(2)(iv) would require States to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency to be included in the payment rate disclosure in proposed paragraph (b)(3)(ii). The second provision in paragraph (b)(6), discussed in the next section, would require States to establish an interested parties' advisory committee to advise and consult on rates paid to certain HCBS providers. This provision is intended to help contextualize lived experience of direct care workers and beneficiaries who receive the services they deliver by providing direct care workers, beneficiaries and their authorized representatives, and other interested parties with the ability to make to recommendations to the Medicaid agency regarding the sufficiency of Medicaid payment rates for these specified services to help ensure sufficient provider participation so that these HCBS are accessible to beneficiaries consistent with section 1902(a)(30)(A) of the Act.

The proposed payment rate disclosure would require States to publish the average hourly payment rates made to individual providers and to providers employed by an agency, separately, if the rates vary, for each category of services specified in paragraph (b)(2)(iv) of this section. No comparison to Medicare payment rates would be required in recognition that Medicare generally does not cover and pay for these services, and when these services are covered and paid for by Medicare, the services are very limited and provided on a short-term basis, rather than long-term basis as with Medicaid HCBS. While Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or

¹⁴³ https://www.kff.org/coronavirus-covid-19/event/march-30-web-event-unsung-heroes-the-crucial-role-and-tenuouscircumstances-of-home-health-aides-during-the-pandemic/; https://www.macpac.gov/wp-content/uploads/2022/03/MACPACbrief-on-HCBS-workforce.pdf.

Medicare Part B (Medical Insurance), Medicare does not cover personal care or homemaker services. 144

We propose to require these services be subject to a payment rate disclosure because this proposed rule aims to standardize data and monitoring across service delivery systems with the goal of improving access to care. To remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e), where we propose to require annual State reporting on access and payment adequacy metrics for homemaker, home health aide, and personal care services, we are proposing to include these services, provided by individual providers and providers employed by an agency in the FFS payment rate disclosure proposed in § 447.203(b)(2). As described earlier in the HCBS provisions of this rule, these specific services were chosen because we expect them to be most commonly conducted in individuals' homes and general community settings and, therefore, constitute the vast majority of FFS payments for direct care workers delivering services under FFS. We acknowledge that the proposed analyses required of States in the HCBS provisions at § 441.311(d)(2) and (e) and in the FFS provisions at § 447.203(b)(2) are different, although, unique to assessing access in each program and delivery system. We are proposing to include personal care, home health aide, and homemaker services for consistency with HCBS access and payment adequacy provisions in this proposed rule, and also to include these services in the proposed provisions of § 447.203(b)(2) to require States to conduct and publish a payment rate disclosure. We believe the latter proposal is important because the payment rate disclosure of personal care, home health aide, and homemaker services would provide CMS with sufficient information, including average hourly payment rates, claims volume, and number of Medicaid enrolled beneficiaries who received a service as specified in proposed § 447.203(b)(3)(ii), from States for ensuring compliance with section 1902(a)(30)(A) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care and sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that

¹⁴⁴ https://www.medicare.gov/coverage/home-health-services.

such care and services are available to the general population in the geographic area.

Additionally, this proposal to include personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency is supported by the statutory mandate at section 2402(a) of the Affordable Care Act. Among other things, section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that ensure that there is an adequate number of qualified direct care workers to provide self-directed services. We are seeking public comment on personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the payment rate disclosure requirements in proposed § 447.203(b)(2)(iv).

After discussing our proposed categories of services for the comparative payment rate analysis and payment rate disclosure requirements, we discuss the similarities and differences between the proposed rule and services currently included in the existing AMRP requirements. While this proposed rule would eliminate the triennial AMRP process, there are some similarities between the service categories for which we are proposing to require a comparative payment rate analysis or payment rate disclosure in § 447.203(b)(2) and those subject to the current AMRP requirements under § 447.203(b)(5)(ii). Specifically, § 447.203(b)(5)(ii)(A) currently requires the State agency to use data collected through the AMRP to provide a separate analysis for each provider type and site of service for primary care services (including those provided by a physician, FOHC, clinic, or dental care). We are proposing the comparative payment rate analysis include primary care services, without any parenthetical description. We believe this is appropriate because the proposed rule includes a comparative payment rate analysis that is at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, the specifics for which are discussed later in this section. This approach requires States to perform less sub-categorization of the data analysis, and as discussed later the analysis, would exclude FOHCs and clinics.

The current AMRP process also includes in § 447.203(b)(5)(ii)(C) behavioral health services (including mental health and substance use disorder); however, this proposed rule specifies that the comparative payment rate analysis only would include outpatient behavioral health services to narrow the scope of the analysis by excluding inpatient behavioral health services (including inpatient behavioral health services furnished in psychiatric residential treatment facilities, institutions for mental diseases, and psychiatric hospitals). While we acknowledge that behavioral health services encompass a broad range of services provided in a wide variety of settings, from outpatient screenings in a physician's office to inpatient hospital treatment, we are proposing to narrow the scope of behavioral health services to just outpatient services to focus the comparative payment rate analysis on ambulatory care provided by practitioners in an office-based setting without duplicating existing requirements, or analysis that must be completed to satisfy existing requirements, for upper payment limits (UPL) and the supplemental payment reporting requirements under section 1903(bb) of the Act, as established by Division CC, Title II, Section 202 (section 202) of the Consolidated Appropriations Act, 2021 (CAA) (P.L. 116-260).

The proposed categories of services in this rule are delivered as ambulatory care where the patient does not need to be hospitalized to receive the service being delivered. Particularly for behavioral health services, we propose to narrow the scope to outpatient behavioral health services to maintain consistency within the categories of service included in the proposed comparative payment rate analysis and payment rate disclosure all being classified as ambulatory care. Additionally, as discussed further in this section of the proposed rule, we proposed that the comparative payment rate analysis would be conducted on a CPT/HCPCS code level, focusing on E/M codes. By narrowing the comparative payment rate analysis to E/M CPT/HCPCS codes, we are proposing States' analyses includes a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii). To balance State administrative burden with our oversight of

State compliance with the access requirement in section 1902(a)(30)(A) of the Act, we are also proposing to limit the services to those delivered primarily by physicians and NPPs in an officebased setting for primary care, obstetrical and gynecological, and outpatient behavioral health services. By excluding facility-based services, particularly inpatient behavioral health services, we intend to ensure the same E/M CPT/HCPCS code-level methodology could be used for all categories of services included in the proposed comparative payment rate analysis, including the use of E/M CPT/HCPCS codes used for outpatient behavioral health services. Rather than fee schedule rates, States often pay for inpatient behavioral health services using prospective payment rate methodologies, such as Diagnosis Related Groups (DRGs), or interim payment methodologies that are reconciled to actual cost. 145 These methodologies pay for a variety of services delivered by multiple providers that a patient receives during an inpatient hospital stay, rather than a single ambulatory service billed by a single provider using a single CPT/HCPCS code. Variations in these payment methodologies and what is included in the rate could complicate the proposed comparison to FFS Medicare rates for the services identified in paragraphs (b)(2)(i) through (iii) and could frustrate comparisons between States and sometimes even within a single State. Therefore, we do not believe the E/M CPT/HCPCS code level methodology proposed for the comparative payment rate analysis would be feasible for inpatient behavioral health services or other inpatient and facility-based services in general.

While we considered including inpatient behavioral health services as one of the proposed categories of services in the comparative payment rate analysis, we ultimately did not because we already collect and review Medicaid and Medicare payment rate data for inpatient behavioral health services through annual upper payment limits demonstrations (UPL) and supplemental payment reporting requirements under section 1903(bb) of the Act. SMDL 13-003 discusses the annual submission of State UPL demonstrations for inpatient hospital services,

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 $^{^{145}\} https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/Design_and_development_of_the_Diagnosis_Related_Group_(DRGs).pdf.$

among other services, including a complete data set of payments to Medicaid providers and a reasonable estimate of what Medicare would have paid for the same services. 146,147 UPL requirements go beyond the proposed requirements in this rule by requiring States to annually submit the following data for all inpatient hospital services, depending on the State's UPL methodology, on a provider level basis: Medicaid charges, Medicaid base payments, Medicaid supplemental payments, Medicaid discharges, Medicaid case mix index, Medicaid inflation factors, other adjustments to Medicaid payments, Medicaid days, Medicare costs, Medicare payments, Medicare discharges, Medicare case mix index, Medicare days, UPL inflation factors, Medicaid provider tax cost, and other adjustments to the UPL amount. If we proposed inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis, then this proposed rule would require States to biennially submit the following data for only inpatient behavioral health services on a CPT/HCPCS code level basis: Medicaid base payment rates for select E/M CPT/HCPCS codes (accounting for rate variation based on population (pediatric and adult), provider type, and geographical location, as applicable), the corresponding Medicare payment rates, Medicaid base payment rate as a percentage of Medicare payment rate, and the number of Medicaid-paid claims. While the UPL requires aggregated total payment and cost data at the provider level and the comparative payment rate analysis would require more granular base payment data at the CPT/HCPCS code level, the UPL overall requires aggregate Medicaid provider payment data for both base and supplemental payments as well as more detailed data for calculating what Medicare would have paid as the upper payment amount. Therefore, proposing to require States include Medicaid and Medicare payment rate data for inpatient behavioral health services in the comparative payment rate analysis would be duplicative of existing UPL requirements that are inclusive of and more comprehensive than the payment information proposed in the comparative payment rate analysis.

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¹⁴⁶ https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.

¹⁴⁷ If a State's payment methodology describes payment at no more than 100 percent of the Medicare rate for the period covered by the UPL, then the State does not need to submit a demonstration. See FAQ ID: 92201. https://www.medicaid.gov/faq/index.html?search_api_fulltext=ID%3A92201&sort_by=field_faq_date&sort_order=DESC.

Additionally, section 1903(bb) of the Act requires us to establish a Medicaid supplemental payment reporting system that collects detailed information on State Medicaid supplemental payments, including total quarterly supplemental payment expenditures per provider; information on base payments made to providers that have received a supplemental payment; and narrative information describing the methodology used to calculate a provider's payment, criteria used to determine which providers qualifies to receive a payment, and explanation describing how the supplemental payments comply with section 1902(a)(30)(A) of the Act. Section 1903(bb)(1)(C) of the Act requires us to make State-reported supplemental payment information publicly available. For States making or wishing to make supplemental payments, including for inpatient behavioral health services, States must report supplemental payment information to us and we must make that information public and, therefore, transparent. Though this proposed rule seeks to increase transparency, with the proposed provisions under § 447.203(b)(1) through (5) focusing on transparency of FFS Medicaid base payment rates, including inpatient behavioral health services as a category of service in § 447.203(b)(2) subject to the comparative payment rate analysis would be duplicative of the existing upper payment limit and supplemental payment reporting requirements, which capture and make transparent base and supplemental payment information for inpatient behavioral health services. However, we are seeking public comment regarding our decision not to include inpatient behavioral health services as one of the categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2) in the final rule, should we finalize the comparative payment rate analysis proposal.

The AMRP process also currently includes in § 447.203(b)(5)(ii)(D) pre- and post-natal obstetric services including labor and delivery; we are proposing to include these services in the comparative payment rate analysis requirements under proposed § 447.203(b)(2)(ii), but intend to broaden the scope of this category of services to include both obstetrical and gynecological services. This expanded proposed provision would capture a wider array of services, both

obstetrical and gynecological services, for States and CMS to assess and ensure access to care in Medicaid FFS is at least as great for beneficiaries as is generally available to the general population in the geographic area, as required by with section 1902(a)(30)(A) of the Act. Lastly, similar to current § 447.203(b)(5)(ii)(E), which specifies that Home health services are included in the AMRP process, we are proposing to include personal care, home health aide, and homemaker services, provided by individual providers and providers employed by an agency. This refined proposed provision would help ensure a more standardized effort to monitor access across Medicaid delivery systems, including for Medicaid-covered LTSS. We believe this proposal also addresses public comments received in response to the February 2022 RFI.¹⁴⁸ Many commenters highlighted the workforce crisis among direct care workers and the impact on HCBS. Specifically, commenters indicated that direct care workers receive low payment rates, and for agency-employed direct care workers, home health agencies often cite low Medicaid payment as a barrier to raising wages for workers. Commenters suggested that States should be collecting and reporting to CMS the average of direct care worker wages while emphasizing the importance of data transparency and timeliness. We are responding to these public comments through this proposed rule by proposing to require States to transparently publish a payment rate disclosure that collects and reports the average hourly rate paid to individual providers and providers employed by an agency for services provided by certain direct care workers (personal care, home health aide, and homemaker services).

In public comments that we received during the public comment period for the 2015 final rule with comment period, many commenters requested that we require States to publish access to care analyses for pediatric services, including pediatric primary care, behavioral health, and dental care. At the time, we responded that pediatric services did not need to be specified in the required service categories because States were already required through § 447.203(b)(1)(iv) to

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¹⁴⁸ Summary of Public Comments in response to the CMS 2022 Request for Information: Access to Coverage and Care in Medicaid & CHIP. December 2022. For the report, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-report.pdf.

consider the characteristics of the beneficiary population, "including . . . payment variations for pediatric and adult populations," within the AMRPs. 149 Although we are proposing to eliminate the AMRP requirements, our proposed rule continues to include special considerations for pediatric populations that are addressed in the discussion of proposed paragraph (b)(2).

We are proposing to eliminate the following from the current AMRP process without replacement in the proposed comparative payment rate analysis requirement, § 447.203(b)(5)(ii)(F): Any additional types of services for which a review is required under current § 447.203(b)(6); § 447.203(b)(5)(ii)(G): Additional types of services for which the State or CMS has received a significantly higher than usual volume of beneficiary, provider or other interested party access complaints for a geographic area, including complaints received through the mechanisms for beneficiary input consistent with current § 447.203(b)(7); and § 447.203(b)(5)(ii)(H): Additional types of services selected by the State.

We propose to eliminate § 447.203(b)(5)(ii)(F) and (G) without a direct replacement because the proposed State Analysis Procedures for Rate Reduction or Restructuring described in § 447.203(c) are inclusive of and more refined than the current AMRP requirements for additional types of services for which a review is required under current § 447.203(b)(6). Specifically, as discussed later in this section, we are proposing in § 447.203(c)(1) that States seeking to reduce provider payment rates or restructure provider payments would be required to provide written assurance and relevant supporting documentation that three conditions are met to qualify for a streamlined SPA review process, including that required public processes yielded no significant access to care concerns for beneficiaries, providers, or other interested parties, or if such processes did yield concerns, that the State can reasonably respond to or mitigate them, as appropriate. If the State is unable to meet all three of the proposed conditions for streamlined SPA review, including the absence of or ability to appropriately address any access concern raised through public processes, then the State would be required to submit additional

^{149 80} CFR 67576 at 67592.

information to support that its SPA is consistent with the access requirement in section 1902(a)(30)(A) of the Act, as proposed in § 447.203(c)(2). We are proposing to modify this aspect of the current AMRP process, because our implementation experience since the 2017 SMDL has shown that States typically have been able to work directly with the public (including beneficiaries and beneficiary advocacy groups, and providers) to resolve access concerns, which emphasizes that public feedback continues to be a valuable source of knowledge regarding access in Medicaid. We believe this experience demonstrates that public processes that occur before the submission of a payment SPA to CMS often resolve initial access concerns, and where concerns persist, they will be addressed through the SPA submission and our review process, as provided in proposed § 447.203(c). Rather than services affected by proposed provider rate reductions or restructurings (current § 447.203(b)(5)(ii)(F)) and services for which the State or CMS received significantly higher than usual volume of complaints (current § 447.203(b)(5)(ii)(G)) being addressed through an AMRP, these services subject to rate reductions or restructurings and services where a high volume of complaints have been expressed would now be addressed by the State analysis procedures in proposed § 447.203(c). We believe this approach would ensure public feedback is fully considered in the context of a payment SPA, without the need to specifically require a comparative payment rate analysis for the service(s) subject to payment rate reduction or restructuring under proposed § 447.203(b)(2).

Lastly, we propose to eliminate current § 447.203(b)(5)(ii)(H), requiring the AMRP include analysis regarding "Additional types of services selected by the State," without a direct replacement because our implementation experience has shown that the majority of States did not select additional types of service to include in their AMRPs beyond the required services § 447.203(b)(5)(ii)(A) through (G). When assessing which services to include in this proposed rule, we determined that the absence of an open-ended type of service option, similar to § 447.203(b)(5)(ii)(H) is unlikely to affect the quality of the analysis proposed in this rule and therefore, we are not including it in the proposed set of services required for the comparative

payment rate analysis. These shifts in policy were informed by our implementation experience and our consideration of State concerns about the burden and value of the AMRP process.

In paragraph (b)(3), we propose that the State agency would be required to develop and publish, consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, a comparative payment rate analysis and payment rate disclosure. This comparative payment rate analysis is divided into two sections based on the categories of services and the organization of each analysis or disclosure. Paragraph (b)(3)(i) describes the comparative payment rate analysis for the categories of service described in paragraphs (b)(2)(i) through (iii): primary care services, obstetrical and gynecological services, and outpatient behavioral health services. Paragraph (b)(3)(ii) describes the payment rate disclosure for the categories of service described in paragraphs (b)(2)(iv): personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency.

Specifically, in paragraph (b)(3)(i), we propose that for the categories of service described in paragraphs (b)(2)(i) through (iii), the State's analysis would compare the State's Medicaid FFS payment rates to the most recently published Medicare payment rates effective for the same time period for the E/M CPT/HCPCS codes applicable to the category of service. The proposed comparative payment rate analysis of FFS Medicaid payment rates to FFS Medicare payment rates would be conducted on a code-by-code basis at the CPT/HCPCS code level using the most current set of codes published by us. It is intended to provide an understanding of how Medicaid payment rates compare to the payment rates established and updated under the FFS Medicare program.

We would expect to publish the E/M CPT/HCPCS codes to be used for the comparative payment rate analysis in subregulatory guidance along with the final rule, if this proposal is finalized. We propose that we would identify E/M CPT/HCPCS codes to be included in the comparative payment rate analysis based on the following criteria: the code is effective for the

same time period of the comparative payment rate analysis; the code is classified as an E/M CPT/HCPCS code by the American Medical Association (AMA) CPT Editorial Panel; the code is included on the Berenson-Eggers Type of Service (BETOS) code list effective for the same time period as the comparative payment rate analysis and falls into the E/M family grouping and families and subfamilies for primary care services, obstetrics and gynecological services, and outpatient behavioral services; and the code has an A (Active), N (Non-Covered), R (Restricted), or T (Injections) code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount for the same time period of the comparative payment rate analysis. 150,151,152

The CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis would classify each E/M CPT/HCPCS code into a corresponding category of service as described in proposed § 447.203(b)(2)(i) through (iii). As previously discussed, by narrowing the comparative payment rate analysis to CMS-specified E/M CPT/HCPCS codes, we are proposing States' analyses include a broad range of core services which would cover a variety of commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii), while also limiting the services to those delivered primarily by physicians and NPPs in an office-based setting. Based on the categories of services specified in proposed § 447.203(b)(2)(i) through (iii), we expect the selected E/M CPT/HCPCS codes to fall under mandatory Medicaid benefit categories, and therefore, we expect that all States would cover and pay for the selected E/M CPT/HCPCS codes. To clarify, we did not narrow the list of E/M CPT/HCPCS codes to those with an A (Active), N (Non-Covered), R (Restricted), or T code status on the Medicare PFS with a Medicare established relative value unit (RVU) and payment amount on the basis of Medicare coverage of a particular code. We are cognizant that codes with N (Non-Covered), R (Restricted), or T code statuses have limited or no Medicare

¹⁵⁰ https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management.

¹⁵¹ https://data.cms.gov/provider-summary-by-type-of-service/provider-service-classifications/restructured-betos-classification-

¹⁵² https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched.

coverage, however, Medicare may establish RVUs and payment amounts for these codes. Therefore, when Medicare does establish RVUs and payment amounts for codes with N (Non-Covered), R (Restricted), or T (Injections) code statuses on the Medicare PFS, we are proposing to include these codes in the comparative payment rate analysis in order to ensure the analysis includes a comprehensive set of codes, for example pediatric services, including well child visits (for example, 99381 through 99384), that are commonly provided services that fall into the categories of service proposed in paragraphs (b)(2)(i) through (iii) and delivered primarily by physicians and NPPs in an office-based setting, as previously described.

As discussed later in this rule, we propose that the comparative payment rate analysis would be updated no less than every 2 years. Therefore, prior to the start of the calendar year in which States would be required to update their comparative payment rate analysis, we would intend to publish an updated list of E/M CPT/HCPCS codes for States to use for their comparative payment rate analysis updates through subregulatory guidance. The updated list of E/M CPT/HCPCS codes would incorporate changes made by to the AMA CPT Editorial Panel (such as additions, removals, or amendments to a code definition where there is a change in the set of codes classified as an E/M CPT/HCPCS code billable for primary care services, obstetrics and gynecological services, or outpatient behavioral services) and changes to the Medicare PFS based on the most recent Medicare PFS final rule (such as changes in code status or creation of Medicare-specific codes).¹⁵³

We intend to publish the initial and subsequent updates of the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis, if this proposal is finalized. We are aware that Medicare may issue a correction to the Medicare PFS after the final rule is in effect, and this correction may impact our published list of E/M CPT/HCPCS codes. In

 $^{^{153}\} https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.$

this instance, for codes included on our published list of E/M CPT/HCPCS codes that are affected by a correction to the most recent Medicaid PFS final rule, we may add or remove an E/M CPT/HCPCS code from the published list, as appropriate, depending on the change to the Medicare PFS. Alternatively, depending on the nature of the change, we would expect States to accurately identify which code(s) are used in the Medicaid program during the relevant period that best correspond to the CMS-identified E/M CPT/HCPCS code(s) affected by the Medicare PFS correction. We would expect States to rely on the CMS published list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis for complying with the proposed requirements in paragraphs (b)(2) through (4).

We acknowledge that there are limitations to relying on E/M CPT/HCPCS codes to select payment rates for comparative payment rate analysis to aid States, CMS, and other interested parties in assessing if payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Providers across the country and within each State deliver a variety of services to patients, including individuals with public and private sources of coverage, and then bill them under a narrow subset of CPT/HCPCS codes that fit into the E/M classification as determined by the AMA CPT Editorial Panel. The actual services delivered can require a wide array of time, skills, and experience of the provider which must be represented by a single five digit code for billing to receive payment for the services delivered. While there are general principles that guide providers in billing the most representative E/M CPT/HCPCS code for the service they delivered, two providers might perform substantially similar activities when delivering services and yet bill different E/M CPT/HCPCS codes for those activities, or bill the same E/M CPT/HCPCS code for furnishing two very different services. The E/M CPT/HCPCS code itself is not a tool for capturing the exact service that was delivered, but medical documentation helps support the billing of a particular E/M CPT/HCPCS code.

Although they do not encompass all Medicaid services covered and paid for in the Medicaid program which are subject to the requirements in section 1902(a)(30)(A) of the Act, E/M CPT/HCPCS codes are some of the most commonly billed codes and including them in the comparative payment rate analysis would allow us to uniformly compare Medicaid payment rates for these codes to Medicare PFS rates. As such, to balance administrative burden on States and our enforcement responsibilities, we are proposing to use E/M CPT/HCPCS codes in the comparative payment rate analysis to define the parameters of our analysis to how much Medicaid and the FFS Medicare program would pay for services that can be classified into a particular E/M CPT/HCPCS code. We are seeking public comment on the proposed comparative payment rate analysis requirement in § 447.203(b)(3)(i), including the proposed requirement to conduct the analysis at the CPT/HCPCS code level, the proposed criteria that we would apply in selecting E/M CPT/HCPCS codes for inclusion in the required analysis, and the proposed requirement for States to compare Medicaid payment rates for the selected E/M CPT/HCPCS codes to the most recently published Medicare non-facility payment rate as listed on the Medicare PFS effective for the same time period which is discussed in more detail later in this rule when describing the proposed provisions of § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i), we further propose that the State's comparative payment rate analysis would be required to meet the following requirements: (A) the analysis must be organized by category of service as described in § 447.203(b)(2)(i) through (iii); (B) the analysis must clearly identify the Medicaid base payment rates for each E/M CPT/HCPCS code identified by us under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable; (C) the analysis must clearly identify the Medicare PFS non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B); (D) the analysis must specify

the Medicaid payment rate identified under paragraph (b)(3)(i)(B) as a percentage of the Medicare payment rate identified under paragraph (b)(3)(i)(C) for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B); and (E) the analysis must specify the number of Medicaid-paid claims within a calendar year for each of the services for which the Medicaid payment rate is published under paragraph (b)(3)(i)(B). We are seeking public comment on the proposed requirements and content of the items in proposed § 447.203(b)(3)(i)(A) through (E).

In paragraph (b)(3)(i)(A), we propose to require States to organize their comparative payment rate analysis by the service categories described in paragraphs (b)(2)(i) through (iii) of this section. This proposed requirement is included to ensure the analysis breaks out the payment rates for primary care services, obstetrical and gynecological services, and outpatient behavioral health services separately for individual analyses of the payment rates for each CMS-selected E/M CPT/HCPCS code, grouped by category of service. We are seeking public comment on the proposed requirement for States to break out their payment rates at the CPT/HCPCS code level for primary care services, obstetrical and gynecological services, and outpatient behavioral health services, separately, in the comparative payment rate analysis as specified in proposed § 447.203(b)(3)(i)(A).

In paragraph (b)(3)(i)(B), after organizing the analysis by § 447.203(b)(2)(i) through (iii) categories of service and CMS-specified E/M CPT/HCPCS code, we propose to require States to clearly identify the Medicaid base payment rate for each code, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. We propose that the Medicaid base payment rate in the comparative payment rate analysis would only include the State's Medicaid fee schedule rate, that is, the State's Medicaid base rate for each E/M CPT/HCPCS code. By specifying the services included in the comparative payment rate analysis by E/M CPT/HCPCS code, we expect the Medicaid base payment rate in the comparative payment rate analysis would only include the

State's Medicaid fee schedule rate for that particular E/M CPT/HCPCS code as published on the State's Medicaid fee schedule effective for the same time period covered by the comparative payment rate analysis. As an example, the State's Medicaid fee schedule rate as published on the Medicaid fee schedule effective for the time period of the comparative payment rate analysis for 99202 is listed as \$50.00. This rate would be the Medicaid base payment rate in the State's comparative payment rate analysis for comparison to the Medicare non-facility rate which is discussed later in this section.

Medicaid base payment rates are typically determined through one of three methods: the resource-based relative value scale (RBRVS), a percentage of Medicare's fee, or a State-developed fee schedule using local factors. The RBRVS system, initially developed for the Medicare program, assigns a relative value to every physician procedure based on the complexity of the procedure, practice expense, and malpractice expense. States may also adopt the Medicare fee schedule rate, which is also based on RBRVS, but select a fixed percentage of the Medicare amount to pay for Medicaid services. States can develop their own PFSs, typically determined based on market value or an internal process, and often do this in situations where there is no Medicare or private payer equivalent or when an alternate payment methodology is necessary for programmatic reasons. States often adjust their payment rates based on provider type, geography, site of services, patient age, and in-State or out-of-State provider status. Additionally, Medicaid base payment rates can be paid to physicians in a variety of settings, including clinics, community health centers, and private offices.

We acknowledge that only including Medicaid base payments in the analysis does not necessarily represent all of a provider's revenues that may be related to furnishing services to Medicaid beneficiaries, and that other revenues not included in the proposed comparative analysis may be relevant to a provider's willingness to participate in Medicaid (such as beneficiary cost sharing payments, disproportionate share hospital payments for qualifying

154 https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf.

hospitals, supplemental payments, etc.). Public comments we received on the 2011 proposed rule and responded to in the 2015 final rule with comment period regarding the AMRPs expressed differing views regarding which provider "revenues" should be included within comparisons of Medicaid to Medicare payment rates. One commenter "noted that the preamble of the 2011 proposed rule refers to 'payments' and 'rates' interchangeably but that courts have defined payments to include all Medicaid provider revenues rather than only Medicaid FFS rates." The commenter stated that if the final rule consider[ed] all Medicaid revenues received by providers, States may be challenged to make any change to the Medicaid program that might reduce provider revenues." This proposed rule narrows the Medicaid base payment rates to the amount listed on the State's fee schedule in order for the comparative payment rate analysis to accurately and analogously compare Medicaid fee schedule rates to Medicare fee schedule rates as listed on the Medicare PFS.

We believe this proposal represents the best way to create a consistent metric across

States against which to evaluate access. To be specific, we are not proposing to include supplemental payments in the comparative payment rate analysis. Requiring supplemental payment data be collected and included under this rule would be duplicative of existing requirements. State supplemental payment and DSH payment data are already subject to our review in various forms, such as through DSH audits for DSH payments, and through annual upper payment limits demonstrations, and through supplemental payment reporting under section 1903(bb) of the Act. 156,157 As such, we do not see a need to add additional reporting requirements concerning supplemental payments as part of the proposals in this rulemaking to allow us the opportunity to review the data. Also, supplemental payments are often made for specific Medicaid-covered services and targeted to a subset of Medicaid-participating providers;

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^{155 80} FR 67576 at 67581.

 ¹⁵⁶ CMS State Medicaid Director Letter: SMDL 13-003. March 2013. Federal and State Oversight of Medicaid Expenditures.
 Available at https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/SMD-13-003-02.pdf.
 157 CMS State Medicaid Director Letter: SMDL 21-006. December 2021. New Supplemental Payment Reporting and Medicaid Disproportionate Share Hospital Requirements under the Consolidated Appropriations Act, 2021. Available at https://www.medicaid.gov/federal-policy-guidance/downloads/smd21006.pdf.

not all Medicaid-participating providers, and not all providers of a given Medicaid-covered service, may receive supplemental payments in a State. Therefore, including supplemental payments in the comparative payment rate analysis would create additional burden for States without then also providing an accurate benchmark of how payments may affect beneficiary access due to the potentially varied and uneven distribution of supplemental payments.

Accordingly, we are proposing to require that States conduct the comparative payment rate analysis for only Medicaid base payment rates for selected E/M CPT/HCPCS codes. For each proposed category of service listed in paragraphs (b)(2)(i) through (iii), this would result in a transparent and parallel comparison of Medicaid base payment rates that all

Medicaid-participating providers of the service would receive to the payment rates that Medicare would pay for the same E/M CPT/HCPCS codes.

Additionally, in paragraph (b)(3)(i)(B), we propose that, if the States' payment rates vary, the Medicaid base payment rates must include a breakdown by payment rates paid to providers delivering services to pediatric and adult populations, by provider type, and geographical location, as applicable, to capture this potential variation in the State's payment rates. This proposed provision to breakdown the Medicaid payment rate is first stated in proposed paragraph (b)(2) and carried through in proposed paragraph (b)(3)(i)(B) to provide clarity to States about how the Medicaid payment rate should be reported in the comparative payment rate analysis.

In paragraph (b)(3)(i)(C), we propose to require States' comparative payment rate analysis clearly identify the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location, that correspond to the Medicaid payment rates identified under paragraph (b)(3)(i)(B), including, separate identification of the payment rates by provider type. We are not proposing to establish a threshold percentage of Medicare non-facility payment rates that States would be required to meet when setting their Medicaid payment rates. Rather, we are proposing to use Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark to which States would

compare their Medicaid payment rates to inform their and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. Benchmarking against FFS Medicare, another of the nation's large public health coverage programs, serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. Similar to Medicaid, Medicare provides health coverage for a significant number of Americans across the country. In December 2022, total Medicaid enrollment was at 85.2 million individuals 158 while total Medicare enrollment was at 65.4 million individuals. 159,160 Both the Medicare and Medicaid programs cover and pay for services provided to beneficiaries residing in every State and territory of the United States. As previously described, Medicare non-facility payment rates as listed on the Medicare PFS for covered, non-covered, and limited coverage services generally are determined on a national level as well as adjusted to reflect the variation in practice costs from one geographical location to another. Medicare also ensures that their payment rate data are publicly available in a format that can be analyzed. The accessibility and consistency of the Medicare non-facility payment rates as listed on the Medicare PFS, compared to negotiated private health insurance payment rates that typically are considered proprietary information and, therefore, not generally available to the public, makes Medicare non-facility payment rates as listed on the Medicare PFS an available and reliable comparison point for States to use in the comparative payment rate analysis.

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¹⁵⁸ https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/December-2022-medicaid-chip-enrollment-trend-snapshot.pdf.

¹⁵⁹ Total Medicare enrollment equals the Tot_Benes variable in the Medicare Monthly Enrollment Data for December (Month) 2022 (Year) at the national level (Bene_Geo_Lvl). Tot_Benes is a count of all Medicare beneficiaries, including beneficiaries with Original Medicare and beneficiaries with Medicare Advantage and Other Health Plans. We utilized the count of all Medicare beneficiaries because Original Medicare, Medicare Advantage, and other Health Plans offer fee-for-service payments to providers. See the Medicare Monthly Enrollment Data Dictionary for more information about the variables in the Medicare Monthly Enrollment Data: https://data.cms.gov/sites/default/files/2023-02/lec24f76-9964-4d00-9e9a-

⁷⁸bd556b7223/Medicare%20Monthly%20Enrollment_Data_Dictionary%2020230131_508.pdf.

160 https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.

Additionally, Medicare is widely accepted nationwide according to recent findings from the National Electronic Health Records Survey. In 2019, 95 percent of physicians accepting new patients overall, and 89 percent of office-based physicians, were accepting new Medicare patients, and the percentage of office-based physicians accepting new Medicare patients has remained stable since 2011 when the value was 88 percent, with modest fluctuations in the years in between. 161 In regards to physician specialties that align with the proposed categories of services in this rule, 81 percent of general practice/family medicine physicians and 81 percent of physicians specializing in internal medicine were accepting new Medicare patients, 93 percent of physicians specializing obstetrics and gynecology were accepting new Medicare patients, and 60 percent of psychiatrists were accepting new Medicare patients in 2019. Although the percentage of psychiatrists who accept Medicare is lower than other types physicians providing services included in the comparative payment rate analysis, this circumstance is not unique to Medicare amongst payers. For example, 60 percent of psychiatrists were also accepting new privately insured patients in 2019. Therefore, the decreased rate of acceptance by psychiatrists relative to certain other physician specialists does not make Medicare an inappropriate benchmark when evaluated against other options for comparison. 162

Historically, Medicare has low rates of physicians formally opting out of the Medicare program with 1 percent of physicians consistently opting out between 2013 and 2019 and of that 1 percent of physicians opting out of Medicare, 42 percent were psychiatrists. This information suggests that Medicare's payment rates generally are consistent with a high level of physician willingness to accept new Medicare patients, with the vast majority of physicians willing to accept Medicare's payment rates. For the reasons previously described, we are

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 $^{^{161}\} https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.$

¹⁶² https://www.kff.org/medicare/issue-brief/faqs-on-mental-health-and-substance-use-disorder-coverage-in-medicare/.
163 Physicians and practitioners who do not wish to enroll in the Medicare program may "opt-out" of Medicare. This means that neither the physician, nor the beneficiary submits the bill to Medicare for services rendered. Instead, the beneficiary pays the physician out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician and the beneficiary that states, that neither one can receive payment from Medicare for the services that were performed. See 2022 opt-out affidavit data published by the Centers for Medicare & Medicaid services: https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opt-out-affidavits.

proposing to use Medicare non-facility payment rates as listed on the Medicare PFS as a national benchmark for States to compare their Medicaid payment rates in the comparative payment rate analysis because we believe that the Medicare payment rates for these services are likely to serve as a reliable benchmark for a level of payment sufficient to enlist providers to furnish the relevant services to an individual. We are seeking public comment on the proposed used of Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

Specifically, in paragraph (b)(3)(i)(C), we propose to require States to compare their Medicaid payment rates to the Medicare non-facility payment rates effective for the same time period as the same set of E/M CPT/HCPCS codes paid under Medicaid as specified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type. We propose to require States to compare their payment rates to the corresponding Medicare PFS non-facility rates because we are seeking a payment analysis that compares Medicaid payment rates to Medicare payment rates at comparable location of service delivery (that is, in a non-clinic, non-hospital, ambulatory setting such as a physician's office). States often pay physicians operating in an office based on their Medicaid fee schedule whereas they may pay physicians operating in hospitals or clinics using an encounter rate. The Medicaid fee schedule rate typically reflects payment for an individual service that was rendered, for example, an office visit that is billed as a single CPT/HCPCS code. An encounter rate often reflects reimbursement for total facility specific costs divided by the number of encounters to calculate a per visit or per encounter rate that is paid to the facility for all services received during an encounter, regardless of which specific services are provided during a particular encounter. For

example, the same encounter rate may be paid for a beneficiary who has an office visit with a physician, a dental examination and cleaning from a dentist, and laboratory tests and for a beneficiary who receives an office visit with a physician and x-rays. Encounter rates are typically paid to facilities, such as hospitals, FQHCs, RHCs, or clinics, many of which function as safety net providers that offer a wide variety of medical services. Within the Medicaid program, encounter rates can vary widely in the rate itself and services paid for through the encounter rate. Proposing States demonstrate the economy and efficiency of their encounter rates would be an entirely different exercise to the fee schedule rate comparison proposed in this rule because encounter rates are often based on costs unique to the provider, and States often require providers to submit cost reports to States for review to support payment of the encounter rate. Comparing cost between the Medicaid and Medicare program would require a different methodology, policies, and oversight than what is proposed in this rule due to the differences within and between each program. While the Medicare program has a broad, national policy for calculating encounter rates for providers, including prospective payment systems for hospitals, FQHCs, and other types of facilities, Medicare calculates these encounter rates differently than States may calculate analogous rates in Medicaid. Therefore, proposing States disaggregate each of their encounter rates and services covered in each encounter rate to compare to Medicare's encounter rates would be challenging for States.

From that logic, we likewise determined that the Medicare non-facility payment rates as listed on the Medicare PFS rate afforded the best point of comparison because it is the most accurate and most analogous comparison of a service-based access analysis using Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark to compare Medicaid fee schedule rates on a CPT/HCPCS code level basis, as opposed to an encounter rate which could include any number of services or specialties. The Medicare non-facility payment rate as listed on the Medicare PFS is described as "... the fee schedule amount when a physician performs a procedure in a non-facility setting such as the office" and "[g]enerally, Medicare gives higher

payments to physicians and other health care professionals for procedures performed in their offices [compared to those performed elsewhere] because they must supply clinical staff, supplies, and equipment."¹⁶⁴ As such, we believe the Medicaid fee schedule best represents the payment intended to pay physicians and non-physician practitioners for delivery of individual services in an office (non-facility) setting, and the Medicare non-facility payment rate as listed on the Medicare PFS represents the best equivalent to that amount and consideration.

For the purposes of the comparative payment rate analysis, we would expect States to source the Medicare non-facility payment rate from the published Medicare fee schedule amounts on the Medicare PFS through one or both of the following sources: the Physician Fee Schedule Look-Up Tool¹⁶⁵ on cms.gov or Excel file downloads of the Medicare PFS Relative Value Files¹⁶⁶ for the relevant calendar year from cms.gov. We encourage States to begin sourcing Medicare non-facility payment rates from the Physician Fee Schedule Look-Up Tool and utilize the Physician Fee Schedule Guide for instructions on using the Look-Up Tool. When codes are not available in the Look-Up Tool, we would direct States to the Excel file downloads of the Medicare PFS Relative Value Files where States can find necessary information for calculating Medicare non-facility payment rates.

As described in the Medicare Claims Processing Manual, most physician services are paid according to the Medicare PFS and the fee schedule amounts for a particular procedure code (including HCPCS, CPT, and CDT) are computed using a resource-based formula made up of three components of a procedure's RVU: physician work, practice expense, and malpractice as well as geographical differences in each locality area of the country. The resource-based formula also includes adjustments to reflect the variation in practice costs from one geographical location to another. Medicare establishes a geographic practice cost index (GPCI) for every Medicare payment locality for each of the three components of a procedure's RVU for physician

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¹⁶⁴ https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.

¹⁶⁵ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup.

¹⁶⁶ https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files.

¹⁶⁷ https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c12.pdf.

work, practice expense, and malpractice and applies the GPCIs in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.¹⁶⁸

Medicare also includes adjustments to the fee schedule amounts, for example, based on site of service (non-facility versus facility setting), where the rate, facility or non-facility, that a physician service is paid under the PFS is determined by the place of service (POS) code that is used to identify the setting where the beneficiary received the face-to-face encounter with the billing practitioner. We are proposing States use the Medicare non-facility payment rate as listed on the Medicare PFS in the comparative payment rate analysis. For codes that are not available in the Look-Up Tool, we would direct States to the Excel file downloads of the Medicare PFS Relative Value Files which include the RVUs, GPCI, and the "National Physician Fee Schedule Relative Value File Calendar Year 2023" file which contains the associated relative value units (RVUs), a fee schedule status indicator, and various payment policy indicators needed for payment adjustment (i.e., payment of assistant at surgery, team surgery, bilateral surgery, etc.). We expect States to utilize the formula for the Non-Facility Pricing Amount in "National Physician Fee Schedule Relative Value File Calendar Year 2023" file to calculate the "Non-Facility Price" using the RVUs, GPCIs, and conversion factors for codes not available in the Look-Up Tool. For codes available in the Look-Up Tool, we expect States to specifically use the Medicare payment rates listed under the "Non-Facility Price" header as described on the Medicare PFS. The Non-Facility Price is the established Medicare payment rate as listed on the Medicare PFS which includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient.

Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. 42 CFR 447.15 defines payment-in-full as "the amounts

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¹⁶⁸ https://www.cms.gov/medicare/physician-fee-schedule/search/overview.

paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual." Therefore, the State's Medicaid base payment rate used for comparison should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to align with the inclusion of expected beneficiary cost sharing in Medicare's non-facility payment rates as listed on the Medicare PFS. 169

In paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rates must be effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section. We included this language to ensure the comparative payment rate analysis is as accurate and analogous as possible by proposing that the Medicaid and Medicare payment rates that are effective during the same time period for the same set of E/M CPT/HCPCS codes. As later described in this rule, in paragraph (b)(4), we propose the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates would be a retroactive analysis of payment rates that are in effect as of January 1, 2025, with the analysis and disclosure published no later than January 1, 2026. For example, the first comparative payment rate analysis a State develops and publishes would compare Medicaid base payment rates in effect as of January 1, 2025, to the Medicare non-facility payment rates effective January 1, 2025, to ensure the Medicare non-facility payment rates are effective for the same time period for the same set of E/M CPT/HCPCS codes that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section.

¹⁶⁹ According to the Medicare Physician Fee Schedule Guide, for most codes, Medicare pays 80% of the amount listed and the beneficiary is responsible for 20 percent.

Additionally, in paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rates as listed on the Medicare PFS used for the comparison must be for the same geographical location as the Medicaid base payment rates. For States that pay Medicaid payment rates based on geographical location (for example, payment rates that vary by rural or non-rural location, by zip code, or by metropolitan statistical area), we propose that States comparative payment rate analysis would need to utilize the Medicare non-facility payment rates as listed on the Medicare PFS for the same geographical location as the Medicaid base payment rates to achieve an equivalent comparison. We would expect States to review Medicare's published listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and identify the comparable Medicare locality area for the same geographical area as the Medicaid base payment rates.¹⁷⁰

We recognize that States that make Medicaid payment based on geographical location may not use the same locality areas as Medicare. For example, a State may use its own State-determined geographical designations, resulting in 5 geographical areas in the State for purposes of Medicaid payment while Medicare recognizes 3 locality areas for the State based on Metropolitan Statistical Area (MSA) delineations determined by the US Office of Management and Budget (OMB) and are the result of the application of published standards to Census Bureau data. ¹⁷¹ In this instance, we would expect the State to determine an appropriate method to accomplish the comparative payment rate analysis that aligns the geographic area covered by each payer's rate as closely as reasonably feasible. For example, if the State identifies two geographic areas for Medicaid payment purposes that are contained almost entirely within one Medicare geographic area, then the State reasonably could determine to use the same Medicare non-facility payment rate as listed on the Medicare PFS in the comparative payment rate analysis for each Medicaid geographic area. As another example, if the State defined a single geographic

170 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.

¹⁷¹ https://www.census.gov/programs-surveys/metro-micro/about/delineation-files.html.

area for Medicaid payment purposes that contained two Medicare geographic areas, then the State might determine a reasonable method to weight the two Medicare payment rates applicable within the Medicaid geographic area, and then compare the Medicaid payment rate for the Medicaid-defined geographic area to this weighted average of Medicare payment rates. Alternatively, as discussed in the next paragraph, the State could determine to use the unweighted arithmetic mean of the two Medicare payment rates applicable within the Medicaid-defined geographic area. We are seeking public comment on the proposed use of Medicare non-facility payment rates as listed on the Medicare PFS as a benchmark for States to compare their Medicaid payment rates to in the comparative payment rate analysis requirements in proposed § 447.203(b)(3)(i) to help assess if Medicaid payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We are aware that States may not determine their payment rates by geographical location. For States that do not pay Medicaid payment rates based on geographical location, we propose that States compare their Medicaid payment rates (separately identified by population, pediatric and adult, and provider type, as applicable) to the Statewide average of Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code. The Statewide average of the Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code would be calculated as a simple average or arithmetic mean where all Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code for a particular State would be summed and divided by the number of all Medicare non-facility payment rates as listed on the Medicare PFS for a particular CPT/HCPCS code for a particular State. This calculated Statewide average of the Medicare non-facility payment rates as listed on the Medicare non-facility payment rates as listed on the Medicare PFS would be calculated for each CPT/HCPCS code subject to the comparative payment rate analysis using the Non-Facility Price for each locality in the State

rates as listed on the Medicare PFS. As previously mentioned, Medicare has published a listing of the current PFS locality structure organized by State, locality area, and when applicable, counties assigned to each locality area and we would expect States to utilize this listing to identify the Medicare locality areas in their State. For example, the Specific Medicare Administrative Contractor (MAC) for Maryland is 12302 and there are two Specific Locality codes, 1230201 for BALTIMORE/SURR. CNTYS and 1230299 for REST OF STATE. When using the Medicare Physician Fee Schedule Look Up Tool to identify the Medicare Non-Facility Price(s) for CY 2023 for 99202 in the Specific MAC locality code for Maryland (12302 MARYLAND), the following search results are populated: Medicare Non-Facility Price of \$77.82 for BALTIMORE/SURR. CNTYS and \$74.31 for REST OF STATE. These two Medicare Non-Facility Price(s) would be averaged to obtain a calculated Statewide average for Maryland of \$76.07.

For States that do not determine their payment rates by geographical location, we propose that States would use the Statewide average of the Medicare Non-Facility Price(s) as listed on the PFS, as previously described, because it ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non-facility payment rates as listed on the Medicare PFS that States use in their comparative payment rate analysis accurately reflect how Medicare pays for services. This proposal ensures that all States' comparative payment rate analyses consistently incorporate Medicare geographical payment rate adjustments as proposed in paragraph (b)(3)(i)(C). As previously discussed, we propose that States that do pay varying rates by geographical location would need to identify the comparable Medicare locality area for the same geographical area as their Medicaid base payment rates. However, for States that do not pay varying rates by geographical location, at the operational level, the State is effectively paying a Statewide Medicaid payment rate, regardless of geographical location, that cannot be matched to

 $^{^{172}\} https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0\&T=4\&HT=0\&CT=1\&H1=99202\&C=43\&M=5.$

a Medicare non-facility payment rate in a comparable Medicare locality area for the same geographical area as the Medicaid base payment rates. Therefore, in order consistently apply the proposed provision that the Medicare non-facility payment rate must be for the same geographical location as the Medicaid base payment rates, States that do not pay varying rates by geographical location would be required to calculate a Statewide average of the Medicare non-facility payment rate to compare the State's Statewide Medicaid payment rate.

Additionally, we propose that States that do not determine their payment rates by geographical location should use the Statewide average of the Medicare non-facility payment rates as listed on the Medicare PFS to align the implementing regulatory text with the statute's geographic area requirement in section 1902(a)(30)(A) of the Act. Section 1902(a)(30)(A) of the Act requires that Medicaid payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area. Therefore, the proposed provisions of this rule, which are implementing section 1902(a)(30)(A) of the Act, must include a method of ensuring we have sufficient information for determining sufficiency of access to care as compared to the general population in the geographic area. As we have proposed to use Medicare non-facility payment rates as a benchmark for comparing Medicaid base payment rates, we believe that utilizing a Statewide average of Medicare non-facility payment rates as listed on the Medicare PFS for States that do not pay varying rates by geographical location would align the geographic area requirement of section 1902(a)(30)(A) of the Act, treating the entire State (throughout which the Medicaid base payment rate applies uniformly) as the relevant geographic area.

We considered requiring States weight the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate, but we did not propose this due to the additional administrative burden this would create for States complying with the proposed comparative payment rate analysis as well as limited

availability of Medicare beneficiary and claims data necessary to weight the Statewide average of the Medicare non-facility payment rates as described above. As proposed, States that do not determine their payment rates by geographical location would be required to consider Medicare's geographically determined payment rates by Statewide average of the Medicare non-facility payment rates. We believe that proposing an additional step to weight the Statewide average by the proportion of the Medicare beneficiary population covered by each rate would create would not result in a practical version of the Medicare non-facility payment rate for purposes of the comparative payment rate analysis. Additionally, proposing only States that do not determine their payment rates by geographical location would result in additional administrative burden that is not imposed on States who do determine their payment rates by geographical location. Additionally, in order to accurately weight the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate, States would likely require Medicare-paid claims data for each code subject to the comparative payment rate analysis, broken down by each of the comparable Medicare locality areas for the same geographical area as the Medicaid base payment rates that are included in the Statewide average of Medicare non-facility payment rates. While total Medicare beneficiary enrollment data broke down by State and county level is publicly available on data.cms.gov, Medicare-paid claims data broken down by the Medicare locality areas used in the Medicare PFS and by code level is not published by CMS and would be inaccessible for the State to utilize in weighting the Statewide average of the Medicare non-facility payment rates by the proportion of the Medicare beneficiary population covered by each rate. As proposed, we believe that States that do not determine their payment rates by geographical location calculating simple Statewide average of the Medicare non-facility rates in their State ensures consistency across all States' comparative payment rate analysis, aligns with the geographic area requirement of section 1902(a)(30)(A) of the Act, and ensures the Medicare non facility payment rates as listed on the Medicare PFS that States use in their comparative payment rate analysis accurately reflect how Medicare pays for

services. We are seeking public comment regarding our decision not to propose requiring States that do not pay varying Medicaid rates by geographical location weight the Statewide average of the Medicare non-facility payment rates by the distribution of Medicare beneficiaries in the State.

Furthermore, in paragraph (b)(3)(i)(C), we propose that the Medicare non-facility payment rate must separately identify the payment rates by provider type. We previously discussed that some States and Medicare pay a percentage less than 100 percent of their fee schedule payment rates to NPPs, including, for example, nurse practitioners, physician assistants, and clinical nurse specialists. To ensure a State's comparative payment rate analysis is as accurate as possible when comparing their Medicaid payment rates to Medicare, we are proposing that States include a breakdown of Medicare's non-facility payment rates by provider type. The proposed breakdown of Medicare's payment rates by provider type would be required for all States, regardless of whether or how the State's Medicaid payment rates vary by provider type, because it ensures the comparative payment rate analysis accurately reflects this existing Medicare payment policy on the Medicare side of the analysis. Therefore, every comparative payment rate analysis would include the following Medicare non-facility payment rates for the same set of E/M CPT/HCPCS codes paid under Medicaid as described in § 447.203(b)(3)(i)(B): the non-facility payment rate as listed on Medicare PFS rate as the Medicare payment rate for physicians and the non-facility payment rate as listed on Medicare PFS rate multiplied by 0.85 as the Medicare payment rate for NPPs.

As previously mentioned in this proposed rule, Medicare pays nurse practitioners, physician assistants, and clinical nurse specialists at 85 percent of the Medicare PFS rate. Medicare implements a payment policy where the fee schedule amounts, including the Medicare non facility payment rates, as listed on the Medicare PFS are reduced to 85 percent when billed by NPPs, including nurse practitioners, physician assistants, and clinical nurse specialists, whereas physicians are paid 100 percent of the fee schedule amounts as listed on the

Medicare PFS.¹⁷³ As proposed, States' comparative payment rate analysis would need to match their Medicaid payment rates for each provider type to the corresponding Medicare non-facility payment rates for each provider type, regardless of the State paying varying or the same payment rates to their providers for the same service. As an example of a State that pays varying rates based on provider type, if a State's Medicaid fee schedule lists a rate of \$100.00 when a physician delivers and bills for 99202, then the \$100.00 Medicaid base payment rate would be compared to 100 percent of the Medicare non-facility payment rate as listed on the Medicare PFS. If the same State's Medicaid fee schedule lists a rate of \$75 when a nurse practitioner delivers and bills for 99202 (or the State's current approved State plan language states that a nurse practitioner is paid 75 percent of the State's Medicaid fee schedule rate), then the \$75 Medicaid base payment rate would be compared to the Medicare non-facility payment rate as listed on the Medicare PFS multiplied by 0.85. Both Medicare non-facility payments rates would need to account for any applicable geographical variation, including the Non-Facility Price as listed on the Medicare PFS for each relevant locality area or the calculated Statewide average of the Non-Facility Price as listed on the Medicare PFS for all relevant areas of a State, as previously discussed in this section, for an accurate comparison to the corresponding Medicaid payment rate. Alternatively, if a State pays the same \$80 Medicaid base payment rate for the service when delivered by physicians and by nurse practitioners, then the \$80 would be listed separately for physicians and nurse practitioners as the Medicaid base payment rate and compared to the Medicare non-facility payment rate as listed on the Medicare PFS for physicians and the Medicare non-facility payment rate as listed on the Medicare PFS multiplied by 0.85 for nurse practitioners.

This granular level of comparison provides States with the opportunity to benchmark their Medicaid payment rates against Medicare as part of the State's and our process for ensuring compliance with section 1902(a)(30)(A) of the Act. For example, a State's comparative payment

173 https://www.cms.gov/files/document/physician-fee-schedule-guide.pdf.

rate analysis may show that the State's Medicaid base payment rate for physicians is 80 percent of the Medicare non-facility payment rate and their Medicaid base payment rate for nurse practitioners is 71 percent of the Medicare non-facility payment rate for NPPs, because the State pays a reduced rate to nurse practitioners. Although Medicare also pays a reduced rate to nurse practitioners, the reduced rate the State pays to nurse practitioners compared to Medicare's reduced rate is still a lower percentage than the physician rate. However, another State's comparative payment rate analysis may show that the State's Medicaid base payment rate for physicians is 95 percent of the Medicare non-facility payment rate and their Medicaid base payment rate for nurse practitioners is 110 percent of the Medicare non-facility payment rate because the State pays all providers the same Medicaid base payment rate while Medicare pays a reduced rate of 85 percent of the Medicare non-facility payment rate as listed on the Medicare PFS when the service is furnished by an NPP. By conducting this level of analysis through the comparative payment rate analysis, States would be able to pinpoint where there may be existing or potential future access to care concerns rooted in payment rates. We are seeking public comment on the proposed requirement for States to compare their Medicaid payment rates to the Medicare non-facility payment rate as listed on the Medicare PFS, effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type, as proposed in § 447.203(b)(3)(i)(C).

In paragraph (b)(3)(i)(D), we propose to require States specify the Medicaid base payment rate identified under proposed § 447.203(b)(3)(i)(B) as a percentage of the Medicare non-facility payment rate identified under proposed § 447.203(b)(3)(i)(C) for each of the services for which the Medicaid base payment rate is published under proposed § 447.203(b)(3)(i)(B). For each E/M CPT/HCPCS code that we select, we propose that States would calculate each Medicaid base payment rate as specified in paragraph (b)(3)(i)(B) as a

percentage of the corresponding Medicare non-facility payment rate specified in paragraph (b)(3)(i)(C). Both rates would be required to be effective for the same time period of the comparative payment rate analysis. As previous components of the proposed comparative payment rate analysis have considered variance in payment rates based on population the service is delivered to (adult or pediatric), provider type, and geographical location to extract the most granular and accurate Medicaid and Medicare payment rate data, we propose that States would calculate the Medicaid base payment rate as a percentage of the Medicare non-facility payment rate in the comparative payment rate analysis to obtain an informative metric that can be used in the State's and our assessment of whether the State's payment rates are compliant with section 1902(a)(30)(A) of the Act. As previously discussed, benchmarking against Medicare serves as an important data point in determining whether payment rates are likely to be sufficient to ensure access for Medicaid beneficiaries at least as great as for the general population in the geographic area, and whether any identified access concerns may be related to payment sufficiency. We propose that States would calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate because it is a common, simple, and informative statistic that can provide us with a gauge of how Medicaid payment rates compare to Medicare non-facility payment rates in the same geographic area. Initially and over time, States, CMS, and other interested parties would be able to compare the State's Medicaid payment rates as a percentage of Medicare's non-facility payment rates to identify how the percentage changes over time, in view of changes that may take place to the Medicaid and/or the Medicare payment rate. Being able to track and analyze the change in percentage over time would help States and CMS identify possible access concerns that may be related to payment insufficiency.

The organization and content of the comparative payment rate analysis, including the expression of the Medicaid base payment rate as a percentage of the Medicare payment rate, can provide us with a great deal of information about access in the State. For example, we would be able to identify when and how the Medicaid base payment rate as a percentage of the Medicare

non-facility payment rate for E/M CPT/HCPCS codes for primary care services may decrease over time if Medicare adjusts its rates and a State does not, and use this information to more closely examine for possible access concerns. This type of analysis would provide us with actionable information to help ensure consistency with section 1902(a)(30)(A) of the Act by using Medicare non-facility payment rates paid across the same geographical areas of the State as a point of comparison for payment rate sufficiency as a critical element of beneficiary access to care. When explaining the rationale for proposing to use Medicare non-facility payment rates for comparison earlier in this rule, we emphasized the ability to demonstrate to States that certain Medicaid payment rates have not kept pace with changes to Medicare non-facility payment rates and how the comparative payment rate analysis would help them identify areas where they also might want to consider rate increases that address market changes. We are seeking public comment on the proposed requirement for States to calculate their Medicaid payment rates as a percentage of the Medicare non-facility payment rate for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as described in proposed § 447.203(b)(3)(i)(D). We are also seeking public comment on any challenges States might encounter when comparing their Medicaid payment rates to Medicare non-facility payment rates under proposed § 447.203(b)(3)(i)(D), particularly for any of the proposed categories of service in paragraphs (b)(2)(i) through (iii), as well as suggestions for an alternative comparative analysis that might be more helpful, or less burdensome and equally helpful, for States, CMS, and other interested parties to assess whether a State's Medicaid payment rates are consistent with the access standard in section 1902(a)(30)(A) of the Act.

We are aware that provider payment rates are an important factor influencing beneficiary access; as expressly indicated in section 1902(a)(30)(A) of the Act, insufficient provider payment rates are not likely to enlist enough providers willing to serve Medicaid beneficiaries to ensure broad access to care; however, there may be situations where access issues are principally due to other causes. For example, even if Medicaid payment rates are generally consistent with

amounts paid by Medicare (and those amounts have been sufficient to ensure broad access to services for Medicare beneficiaries), Medicaid beneficiaries may have difficulty scheduling behavioral health care appointments because the overall number of behavioral health providers within a State is not sufficient to meet the demands of the general population. Therefore, a State's rates may be consistent with the requirements of section 1902(a)(30)(A) of the Act even when access concerns exist, and States and CMS may need to examine other strategies to improve access to care beyond payment rate increases. By contrast, comparing a State's Medicaid behavioral health payment rates to Medicare may demonstrate that the State's rates fall far below Medicare non-facility payment rates, which would likely impede beneficiaries from accessing needed care when the demand already exceeds the supply of providers within a State. In that case, States may need to evaluate budget priorities and take steps to ensure behavioral health rates are consistent with section 1902(a)(30)(A) of the Act.

Lastly, in paragraph (b)(3)(i)(E), we propose to require States to specify in their comparative payment rate analyses the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under paragraph (b)(3)(i)(B). The previous components of the comparative payment rate analysis focus on the State's payment rate for the E/M CPT/HCPCS code and comparing the Medicaid base payment rate to the Medicare non-facility payment rate for the same code (separately, for each Medicaid base payment rate by population (adult or pediatric), provider type, and geographic area, as applicable). This component examines the Medicaid-paid claims volume of each E/M CPT/HCPCS code included in the comparative payment rate analysis relative to the number of Medicaid enrolled beneficiaries receiving each service within a calendar year. We propose to limit the claims volume data to Medicaid-paid claims, and the number of beneficiaries would be limited to Medicaid-enrolled beneficiaries who received a service in the calendar year of the comparative payment rate analysis, where the service would fall into the list of CMS-identified

E/M CPT/HCPCS code(s). In other words, a beneficiary would be counted in the comparative payment rate analysis for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraphs (b)(2)(i) through (iii) for which the State has a Medicaid-based payment rate (the number of Medicaid-enrolled beneficiaries who received a service). A claim would be counted in the comparative payment rate analysis for a particular calendar year when that beneficiary had a claim submitted on their behalf by a provider who billed one of the codes from the list of CMS-identified E/M CPT/HCPCS code(s) to the State and the State paid the claim (number of Medicaid-paid claims). With this proposal, we are seeking to ensure the comparative payment rate analysis reflects actual services received by beneficiaries and paid for by the State, or realized access. 174

We considered but did not propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid-enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B). We considered this detail in order to identify the unique, or deduplicated, number of beneficiaries who received a service that falls into one of the categories of services described in in paragraph (b)(2)(i) through (iii) in a calendar year. For example, if a beneficiary has 6 visits to their primary care provider in a calendar year and the provider bills 6 claims with 99202 for the same beneficiary, then the beneficiary and claims for 99202 would only be counted as one claim and one beneficiary. Therefore, we chose not to propose this aspect because we intend for the comparative payment rate analysis to capture the total amount of actual services received by beneficiaries and paid for by the State. We are seeking public comment regarding our decision not to propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is

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¹⁷⁴ Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

published pursuant to paragraph (b)(3)(i)(B) in comparative payment rate analysis as proposed § 447.203(b)(3)(i)(E).

We also considered but did not propose States identify the total Medicaid-enrolled population who could potentially receive a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B), in addition to the proposing States identify the number of Medicaid-enrolled beneficiaries who received a service. This additional data element in the comparative payment rate analysis would reflect the number of Medicaid-enrolled beneficiaries who could have received a service, or potential access, in comparison to the number of Medicaid-enrolled beneficiaries who actually received a service. We did not propose this aspect because this could result in additional administrative burden on the State, as we already collect and publish similar data through Medicaid and CHIP Enrollment Trends Snapshots published on Medicaid.gov. We are also seeking public comment regarding our decision not to propose States identify the total Medicaidenrolled population who could receive a service within a calendar year for each of the services for each of the services for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) in the comparative payment rate analysis as proposed § 447.203(b)(3)(i)(E).

We propose to include beneficiary and claims information in the comparative payment rate analysis to contextualize the payment rates in the analysis, and to be able to identify longitudinal changes in Medicaid service volume in the context of the Medicaid beneficiary population receiving services, since utilization changes could be an indication of an access to care issue. For example, a decrease in the number of Medicaid-paid claims for primary care services furnished to Medicaid beneficiaries in an area (when the number of Medicaid-enrolled beneficiaries who received primary care services in the area is constant or increasing) could be an indication of an access to care issue. Without additional context provided by the number of Medicaid enrolled beneficiaries who received a service, changes in claims volume could be

attributed to a variety of changes in the beneficiary population, such as a temporary loss of coverage when enrollees disenroll and then re-enroll within a short period of time.

Further, if the Medicaid base payment rate for the services with decreasing Medicaid service volume has failed to keep pace with the corresponding Medicare non-facility payment rate over the period of decrease in utilization (as reflected in changes in the Medicaid base payment rate expressed as a percentage of the Medicare non-facility payment rate as required under proposed § 447.203(b)(3)(i)(D)), then we would be concerned and would further scrutinize whether any access to care issue might be caused by insufficient Medicaid payment rates for the relevant services. With each biennial publication of the State's comparative payment rate analysis, as proposed in § 447.203(b)(4), discussed later in this section, States and CMS would be able to compare the number of paid claims in the context of the number of Medicaid enrolled beneficiaries receiving services within a calendar year for the services subject to the comparative payment rate analysis with previous years' comparative payment rate analyses. Collecting and comparing the number of paid claims data in the context of the number of Medicaid enrolled beneficiaries receiving services alongside Medicaid base payment rate data may reveal trends where an increase in the Medicaid base payment rate is correlated with an increase in service volume and utilization, or vice versa with a decrease in the Medicaid base payment rate is correlated with a decrease in service volume and utilization. As claims utilization and number of Medicaid enrolled beneficiaries receiving services are only correlating trends, we acknowledge that there may be other contextualizing factors outside of the comparative payment rate analysis that affect changes in service volume and utilization and we would (and would expect States and other interested parties to) take such additional factors into account in analyzing and ascribing significance to changes in service volume and utilization. We are seeking public comment on the proposed requirement for States to include the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for

which the Medicaid base payment rate is published under proposed paragraph (b)(3)(i)(B), as specified in proposed § 447.203(b)(3)(i)(E).

We believe the comparative payment rate analysis proposed in paragraph (b)(3) is needed to best enable us to ensure State compliance with the requirement in section 1902(a)(30)(A) of the Act that payments are sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent they are available to the general population in the geographic area. As demonstrated by the findings of Sloan, et al,¹⁷⁵ which have since been supported and expanded upon by numerous researchers, multiple studies examining the relationship between Medicaid payment and physician participation,^{176,177} at the State level,¹⁷⁸ and among specific provider types,^{179,180} have found a direct, positive association between Medicaid payment rates and provider participation in the Medicaid program. While multiple factors may influence provider enrollment (such as administrative burden), section 1902(a)(30)(A) of the Act specifically concerns the sufficiency of provider payment rates. Given this statutory requirement, a comparison of Medicaid payment rates to other payer rates is an important barometer of whether State payment policies are likely to support the statutory standard of ensuring access for Medicaid beneficiaries such that covered care and services are

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¹⁷⁵ Sloan, F. et al "Physician Participation in State Medicaid Programs." *The Journal of Human Resources*, Volume 13, Supplement: National Bureau of Economic Research Conference on the Economics of Physician and Patient Behavior, 1978, p. 211-245. https://www.jstor.org/stable/145253?seq=1#metadata_info_tab_contents. Accessed August 16, 2022.

¹⁷⁶ Chen, A. "Do the Poor Benefit from More Generous Medicaid Policies" SSRN Electronic Journal, January 2014., p. 1-46. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2444286. Accessed June 16, 2022.

¹⁷⁷ Holgash, K. and Martha Heberlein, "Physician Acceptance of New Medicaid Patients: What Matters and What Doesn't" *Health Affairs*, April 10, 2019.

 $https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/\#:\sim:text=Physicians\%E2\%80\%99\%20acceptance\%20of\%20new\%20Medicaid\%20patients\%20already\%20in\%20the\%20physician\%E2\%80\%99s\%20care. Accessed June 16, 2022.$

¹⁷⁸ Fakhraei, H. "Payments for Physician Services: An analysis of Maryland Medicaid Reimbursement Rates" *International Journal of Healthcare Technology and Management, Volume 7*, Numbers 1-2, January 2005, p. 129-142. https://www.researchgate.net/publication/228637758_Payments_for_physician_services_An_analysis_of_Maryland_Medicaid_reimbursement_rates. Accessed June 16, 2022.

¹⁷⁹ Berman, S., et al. "Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients," *Pediatrics*, Volume 110, Issue 2, August 2002, p. 239-248. https://publications.aap.org/pediatrics/article-abstract/110/2/239/64380/Factors-That-Influence-the-Willingness-of-

Private?redirectedFrom=fulltext?autologincheck=redirected. Accessed June 16, 2022.

¹⁸⁰ Suk-fong S., Tang, et al "Increased Medicaid Payment and Participation by Office-Based Primary Care Pediatricians," *Pediatrics*, Volume 141, number 1, January 2018, p. 1-9.

https://publications.aap.org/pediatrics/article/141/1/e20172570/37705/Increased-Medicaid-Payment-and-Participation-by. Accessed June 16, 2022.

available to them at least to the extent that the same care and services are available to the general population in the geographic area.

The AMRP requirements currently address this standard under section 1902(a)(30)(A) of the Act by requiring States to compare Medicaid payment rates to the payment rates of other public and private payers in current § 447.203(b)(1)(v) and (b)(3). While we are proposing to eliminate the AMRP requirements with this proposed rule, we believe that our proposal to require States to compare their Medicaid payment rates for services under specified E/M CPT/HCPCS codes against Medicare non-facility payment rates for the same codes, as described in § 447.203(b)(3), would well position States and CMS to continue to meet the statutory access requirement. Some studies examining the relationship between provider payments and various access measures have quantified the relationship between the Medicaid-Medicare payment ratio and access measures. Two studies observed that increases in the Medicaid-Medicare payment ratio is associated with higher physician acceptance rates of new Medicaid patients and with an increased probability of a beneficiary having an office-based physician as the patient's usual source of care. 181,182 These studies led us to conclude that Medicare non-facility payment rates are likely to be a sufficient benchmark for evaluating access to care, particularly ambulatory physician services, based on provider payment rates.

By comparing FFS Medicaid payment rates to corresponding FFS Medicare non-facility payment rates, where Medicare is a public payer with large populations of beneficiaries and participating providers whose payment rates are readily available, we aim to establish a uniform benchmarking approach that allows for more meaningful oversight and transparency and reduces the burden on States and CMS relative to the current AMRP requirements that do not impose specific methodological standards for comparing payment rates and that contemplate the availability of private payer rate information that has proven difficult for States to obtain due to

¹⁸¹ Holgash, K. and Martha Heberlein, *Health Affairs*, April 10, 2019.

¹⁸² Cohen, J. W., *Inquiry*, Fall 1993.

its often proprietary nature. This aspect of the proposal specifically responds to States' expressed concerns that the AMRP requirement to include "actual or estimated levels of provider payment available from other payers, including other public and private payers" was challenging to accomplish based on the general unavailability of this information, as discussed elsewhere in this proposed rule.

Following the 2011 proposed rule, and as addressed by us through public comment response in the 2015 final rule with comment period, States expressed concerns that private payer payment rates were proprietary information and not available to them and that large private plans did not exist within some States so there were no private payer rates to compare to, therefore, the State would need to rely on State employee health plans or non-profit insurer rates. 183 States also expressed that other payer data, including public and private payers, in general may be unsound for comparisons because of a lack of transparency about the payment data States would have compared their Medicaid payment rates to. Since 2016, we have learned a great deal from our implementation experience of the AMRP process. We have learned that very few States were able to include even limited private payer data in their AMRPs. States that were able include private payer data were only able to do so because the State had existing Statewide all payer claiming or rate-setting systems, which gave them access to private payer data in their State, or the State previously based their State plan payment rates off of information about other payers (such as the American Dental Association's Survey of Dental Fees) that gave them access to private payer data. 184 Based on our implementation experience and concerns from States about the current requirement in § 447.203(b)(1)(v) to obtain private payer data, we are proposing to require States only compare their Medicaid payment rates to Medicare's, for which payment data are readily and publicly available.

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¹⁸³ Alaska Department of Health and Social Services, Comment Letter on 2011 Proposed Rule (July 7, 2011), https://www.regulations.gov/comment/CMS-2011-0062-0102.

¹⁸⁴ https://www.medicaid.gov/sites/default/files/2019-12/co-amrp-2016.pdf, https://www.medicaid.gov/sites/default/files/2019-12/md-amrp-16.pdf, https://www.medicaid.gov/sites/default/files/2019-12/sd-amrp-16.pdf.

Next, in paragraph (b)(3)(ii), we propose that for each category of services described in proposed paragraph (b)(2)(iv), the State agency would be required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates differ. The payment rate disclosure would be required to meet specified requirements. The reason for including this proposal builds on our justification for including personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency in this proposed rule, which is to remain consistent with the proposed HCBS provisions at § 441.311(d)(2) and (e) and take specific action regarding direct care workers per Section 2402(a) of the Affordable Care Act. HCBS and direct care workers that deliver these services are unique to Medicaid and often not covered by other payers, which is why we are proposing a different analysis of payment rates for providers of these services that does not involve a comparison to Medicare. As previously stated, Medicare covers part-time or intermittent home health aide services (only if a Medicare beneficiary is also getting other skilled services like nursing and/or therapy at the same time) under Medicare Part A (Hospital Insurance) or Medicare Part B (Medical Insurance); however, Medicare does not cover personal care or homemaker services. Therefore, comparing personal care and homemaker services to Medicare, as we proposed in paragraph (b)(3)(i) for other specified categories of services, would not be feasible for States, and a comparison of Medicaid home health aide average hourly payment rates to analogous rates for Medicare would be of limited utility given the differences in circumstances when Medicaid and Medicare may pay for such services.

As previously discussed, private payer data are often considered proprietary and not available to States, thereby eliminating private payers as feasible point of comparison. Even if private payer payment rate data were more readily available, like Medicare, many private payers do not cover HCBS as HCBS is unique to the Medicaid program, leaving Medicaid as the largest or the only payer for personal care, home health aide, and homemaker services. Given

Medicaid's status as the most important payer for HCBS, we believe that scrutiny of Medicaid HCBS payment rates themselves, rather than a comparison to other payer rates that frequently do not exist, is most important in ascertaining whether such Medicaid payment rates are sufficient to enlist adequate providers so that the specified services are available to Medicaid beneficiaries at least to the same extent as to the general population in the geographic area. We acknowledge that individuals without insurance may self-pay for medical services provided in their home or community; however, similar to private payer data, self-pay data is unlikely to be available to States. Because HCBS coverage is unique to Medicaid, Medicaid beneficiaries are generally the only individuals in a given geographic area with access to HCBS. Through the proposed payment rate disclosure, Medicaid payments rates would be transparent and comparable among States and would assist States to analyze if and how their payment rates are compliant with section 1902(a)(30)(A) of the Act.

As noted previously in this section, we propose to require States to express their rates separately as the average hourly payments made to individual providers and providers employed by an agency, if the rates differ, as applicable for each category of service specified in proposed § 447.203(b)(2)(iv). We believe expressing the data in this manner would best account for variations in types and levels of payment that may occur in different settings and employment arrangements. Individual providers are often self-employed or contract directly with the State to deliver services as a Medicaid provider while providers employed by an agency are employed by the agency which works directly with the Medicaid agency to provide Medicaid services. These differences in employment arrangements often include differences in the hourly rate a provider would receive for services delivered, for example, providers employed by an agency typically receive benefits, such as health insurance, and the cost of those benefits are factored into the hourly rate that the State pays for the services delivered by providers employed by an agency (even though the employed provider does not retain the entire amount as direct monetary compensation). However, these benefits are not always available for individual providers who

may need to separately purchase a marketplace health plan or be able to opt into the State-employee health plan, for example. Therefore, the provider employed by an agency potentially could receive a higher hourly rate because benefits are factored into the hourly rate they receive for delivering services, whereas the individual provider might be paid a rate that does not reflect employment benefits.

With States expressing their payment rates separately as the average hourly payment rate made to individual and agency employed providers for personal care, home health aide, and homemaker services, States, CMS, and other interested parties would be able to compare payment rates among State Medicaid programs. Such comparisons may be particularly relevant for States in close geographical proximity to each other or that otherwise may compete to attract providers of the services specified in proposed paragraph (b)(2)(iv) or where such providers may experience similar costs or other incentives to provide such services. For example, from reviewing all States' payment rate analyses for personal care, home health aide, and homemaker services, we would be able to learn that two neighboring States have similar hourly rates for providers of these services, but a third neighboring State has much lower hourly rates than both of its neighbors. This information could highlight a potential access issue, since providers in the third State might have an economic incentive to move to one of the two neighboring States where they could receive higher payments for furnishing the same services. Such movement could result in beneficiaries in the third State having difficulty accessing covered services, compared to the general population in the tri-State geographic area.

Additionally in paragraph (b)(3)(ii), we propose that the State's payment rate disclosure must meet the following requirements: (A) the State must organize the payment rate disclosure by category of service as specified in proposed paragraph (b)(2)(iv); (B) the disclosure must identify the average hourly payment rates, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency by population (pediatric and adult), provider type, and geographical

location, as applicable; and (C) the disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published under proposed paragraph (b)(3)(ii)(B). We are seeking public comment on the proposed requirements and content of the items in proposed § 447.203(b)(3)(ii)(A) through (C).

In paragraph (b)(3)(ii)(A), we propose to require States to organize their payment rate disclosures by each of the categories of services specified in proposed paragraph (b)(2)(iv), that is, to break out the payment rates for personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency, separately for individual analyses of the payment rates for each category of service and type of employment structure. We are seeking public comment on the proposed requirement for States to break out their payment rates for personal care, home health aide, and homemaker services separately for individual analyses of the payment rates for each category of service in the comparative payment rate analysis, as described in proposed § 447.203(b)(3)(ii)(A).

In paragraph (b)(3)(ii)(B), we propose to require States identify in their disclosure the Medicaid average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, as well as by population (pediatric and adult), provider type, and geographical location, as applicable. Given that direct care workers deliver unique services in Medicaid that are often not covered by other payers, we are proposing to require a payment rate disclosure, instead of comparative payment rate analysis. To be clear, we are not proposing to require a State's payment rate disclosure for personal care, home health aide, and homemaker services be broken down and organized by E/M CPT/HCPCS codes, nor are we proposing States compare their Medicaid payment rates to Medicare for these services.

We propose to require States calculate their Medicaid average hourly payment rates made to providers of personal care, home health aide, and homemaker services, separately, for each of these categories of services, by provider employment structures (individual providers and agency employed providers). For each of the categories of services in paragraph (b)(3)(ii)(A), one Medicaid average hourly payment rate would be calculated as a simple average or arithmetic mean where all payment rates would be adjusted to an hourly figure, summed, then divided by the number of all hourly payment rates. As an example, the State's Medicaid average hourly payment rate for personal care providers may be \$10.50 while the average hourly payment rate for a home health aide is \$15.00. A more granular analysis may show that within personal care providers receiving a payment rate of \$10.50, an individual personal care provider is paid an average hourly payment rate of \$9.00, while a personal care provider employed by an agency is paid an average hourly payment rate of \$12.00 for the same type of service. Similarly for home health aides, a more granular analysis may show that within home health aides receiving a payment rate of \$15.00, an individual home health aide is paid an average hourly payment rate of \$13.00, while a home health aide employed by an agency is paid an average hourly payment rate of \$15.00.

We understand that States may set payment rates for personal care, home health aide, and homemaker services based on a particular unit of time for delivering the service, and that time may not be in hourly increments. For example, different States might pay for personal care services using 15-minute increments, on an hourly basis, through a daily rate, or based on a 24-hour period. By proposing to require States to represent their rates as an hourly payment rate, we would be able to standardize the unit (hourly) and payment rate for comparison across States, rather than comparing to Medicare. To the extent a State pays for personal care, home health aide, or homemaker services on an hourly basis, the State would simply use that hourly rate in its Medicaid average hourly payment rate calculation of each respective category of service. However, if for example a State pays for personal care, home health aide, or homemaker services on a daily basis, we would expect the State to divide that rate by the number of hours covered by the rate.

Additionally, and similar to proposed paragraph (b)(3)(i)(E), we propose in paragraph (b)(3)(ii)(B), that, if the States' Medicaid average hourly payment rates vary, the rates must separately identify the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable. We include this proposed provision with the intent of ensuring the payment rate disclosure contains the highest level of granularity in each element. As previously discussed, States may pay providers different payment rates for billing the same service based on the population being served, provider type, and geographical location of where the service is delivered. We are seeking public comments on the proposed requirement for States to calculate the Medicaid average hourly payment rate made separately to individual providers and to agency employed providers, which accounts for variation in payment rates by population (pediatric and adult), provider type, and geographical location, as applicable, in the payment rate disclosure as discussed in this section about proposed § 447.203(b)(3)(ii)(B).

In paragraph (b)(3)(ii)(C), we propose to require that the State disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid payment rate is published under proposed paragraph (b)(3)(ii)(B), so that States, CMS, and other interested parties would be able to contextualize the previously described payment rate information with information about the volume of paid claims and number of beneficiaries receiving personal care, home health aide, and homemaker services.

We propose that the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service be reported under the same breakdown as paragraph (b)(3)(ii), where the State provides the number of paid claims and number of beneficiaries receiving services from individual providers versus agency-employed providers of personal care, home health aide services, and homemaker services. As with the comparative payment rate analysis, we are proposing the claims volume data would be limited to Medicaid-paid claims and

the number of beneficiaries would be limited to Medicaid enrolled beneficiaries who received a service in the calendar year of the payment rate disclosure, where the services would fall into the categories of service for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). In other words, beneficiary would be counted in the payment rate disclosure for a particular calendar year when the beneficiary received a service that is included in one of the categories of services described in paragraph (b)(2)(iv) that the State has calculated average hourly payment rates for (the number of Medicaid enrolled beneficiaries who received a service). A claim would be counted when that beneficiary had a claim submitted on their behalf by a provider who billed for one of the categories of services described in paragraph (b)(2)(iv) and the State paid the claim (number of Medicaid-paid claims). We are seeking to ensure the payment rate disclosure reflects actual services received by beneficiaries and paid for by the State, or realized access.¹⁸⁵

Similar to the comparative payment rate analysis, we considered but did not propose States identify the number of unique Medicaid-paid claims and the number of unique Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B). We also considered but did not propose States identify the total Medicaid enrolled population who could receive a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) in addition to the proposing States identify the number of Medicaid enrolled beneficiaries who received a service. As discussed in the comparative payment rate discussion, we are requesting public comment on our decision not to require these levels of detail for the payment rate disclosure.

Also similar to the comparative payment rate analysis requirement under proposed paragraph (b)(3)(i)(E), this disclosure element would help States, CMS, and other interested parties identify

¹⁸⁵ Andersen, R.M., and P.L. Davidson. 2007. Improving access to care in America: Individual and contextual indicators. In Changing the U.S. health care system: Key issues in health services policy and management, 3rd edition, Andersen, R.M., T.H. Rice, and G.F. Kominski, eds. San Francisco, CA: John Wiley & Sons.

longitudinal changes in Medicaid service volume and beneficiary utilization changes that may be an indication of an access to care issue. Again, with each biennial publication of the State's comparative payment rate analysis and payment rate disclosure, States and CMS would be able to compare the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for services subject to the payment rate disclosure with previous years' disclosures. Collecting and comparing data on the number of paid claims and number of Medicaid enrolled beneficiaries alongside Medicaid average hourly payment rate data may reveal trends, such as where a provider type that previously delivered a low volume of services to beneficiaries has increased their volume of services delivered after receiving an increase in their payment rate.

We acknowledge that one limitation of using the average hourly payment rate is that the statistic is sensitive to highs and lows so one provider receiving an increase in their average hourly payment rate would bring up the average overall while other providers may not see an improvement. As these are only correlating trends, we also acknowledge that there may be other contextualizing factors outside of the payment rate disclosure that may affect changes in service volume and utilization. We are seeking public comments on the proposed requirement for States to include the number of Medicaid-paid claims and number of Medicaid enrolled beneficiaries who received a service within a calendar year for which the Medicaid payment rate is published under paragraph (b)(3)(ii)(B), as specified in proposed § 447.203(b)(3)(ii)(C).

Additionally, in recognition of the importance of services provided to individuals with intellectual or developmental disabilities and in an effort to remain consistent with the proposed HCBS provisions at § 441.302(k)(3)(i), we are seeking public comment on whether we should propose a similar provision that would require at least 80 percent of all Medicaid FFS payments with respect to personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency must be spent on compensation for direct care workers.

In paragraph (b)(4), we propose to require the State agency to publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payments in effect as of January 1, 2025, as required under § 447.203(b)(2) and (b)(3), by no later than January 1, 2026. Thereafter, the State agency would be required to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed § 447.203(b)(1) for payment rate transparency data.

As previously discussed in this proposed rule, we propose that the Medicaid payment rates included in the initial comparative payment rate analysis and payment rate disclosure would be those in effect as of January 1, 2025. Specifically, for the comparative payment rate analysis, we propose States would conduct a retrospective analysis to ensure CMS can publish the list of E/M CPT/HCPCS codes for the comparative payment rate analysis and States have timely access to all information required to complete comparative payment rate analysis. As described in paragraph (b)(3)(i)(C), we propose States would compare their Medicaid payment rates to the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, therefore, the Medicare non-facility payment rates as published on the Medicare PFS for the same time period as the State's Medicaid payment rates would need to be available to States in a timely manner for their analysis and disclosure to be conducted and published as described in paragraph (b)(4). Medicare publishes its annual PFS final rule in November of each year and the Medicare non-facility payment rates as listed on the Medicare PFS are effective the following January 1. For example, the 2025 Medicare PFS final rule would be published in November 2024 and the Medicare non-facility payment rates as listed on the Medicare PFS would be effective January 1, 2025, so States would compare their Medicaid payment rates effective as of January 1, 2025, to the Medicare PFS payment rates effective

January 1, 2025 when submitting the initial comparative payment rate analysis that is due on January 1, 2026.

Also previously discussed in this proposed rule, we intend to publish the initial and subsequent updates to the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis in a timely manner that allows States approximately one full calendar year between the publication of the CMS-published list of E/M CPT/HCPCS codes and the due date of the comparative payment rate analysis. Because the list of E/M CPT/HCPCS codes is derived from the relevant calendar year's Medicare PFS, the Medicare non-facility payment rates the State would need to include in their comparative payment rate analysis would also be available to States. We expect approximately one full calendar year of the CMS-published list of E/M CPT/HCPCS codes and Medicare non-facility payment rates as listed on the Medicare PFS being available to States would provide the States with sufficient time to develop and publish their comparative payment rate analyses as described in paragraph (b)(4). We considered proposing the same due date and effective time period for Medicaid and Medicare payment rates where the initial publication of the comparative payment rate analysis would be due January 1, 2026, and would contain payment rates effective January 1, 2026; however, we believe a two month time period between Medicare publishing its PFS payment rates in November and the PFS payment rates taking effect on January 1 would be an insufficient amount of time for CMS to publish the list of E/M CPT/HCPCS codes subject to the comparative payment rate analysis and for States to develop and publish their comparative payment rate analyses by January 1. While the proposed payment rate disclosure would not require a comparison to Medicare, we are proposing to use the same due date and effective period of Medicaid payment rates for both the proposed comparative payment rate analysis and payment rate disclosure to maintain consistency.

We expect the proposed initial publication timeframe to provide sufficient time for States to gather necessary data, perform, and publish the first required comparative payment rate analysis and payment rate disclosure. We determined this timeframe was sufficient based on

implementation experience from the AMRP process, where we initially proposed a 6-month timeframe between the January 4, 2016 effective date of the 2015 final rule with comment period in the Federal Register, and the due date of the first AMRP, July 1, 2016. At the time, we believed that this timeframe would be sufficient for States to conduct their first review for service categories newly subject to ongoing AMRP requirements; however, after receiving several public comments from States on the 2015 final rule with comment period that State agency staff may have difficulty developing and submitting the initial AMRPs within the July 1, 2016 timeframe, we modified the policy as finalized in the 2016 final rule. 186 Specifically, we revised the deadline for submission of the initial AMRP until October 1, 2016 and we made a conforming change to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.187 We also found that, despite this additional time, some State were still late in submitting their first AMRP to us. Therefore, we believe that proposing an initial publication date of January 1, 2026, thereby providing States with approximately 2 years between the effective date of the final rule, if this proposal is finalized, and the due date of the first comparative payment rate analysis and payment rate disclosure, would be sufficient. In alignment with the proposed payment rate transparency requirements, if this rule is finalized at a time that does not allow for States to have a period of 2 years from the effective date of the final rule and the proposed January 1, 2026 date to publish the initial comparative payment rate analysis and payment rate disclosure, then we would propose an alternative date of July 1, 2026 for the initial comparative payment rate analysis and payment rate disclosure and for the initial comparative payment rate analysis and payment rate disclosure to include Medicaid payment rates approved as of July 1, 2025 to allow more time for States to comply with the initial comparative payment rate analysis and payment rate disclosure requirements. We acknowledge that the date of the initial comparative payment rate analysis and payment rate disclosure

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¹⁸⁶ 81 FR 21479 at 21479-21480.

¹⁸⁷ 81 FR 21479 at 21480.

publication is subject to change based on the final rule publication schedule and effective date, if this rule is finalized. If further adjustment is necessary beyond the July 1, 2026 timeframe to allow more time for States to comply with the payment rate transparency requirements, then we would adjust date of the initial payment rate transparency publication in 6-month intervals, as appropriate.

Also, in § 447.203(b)(4), we propose to require the State agency to update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. We propose that the comparative payment rate analysis and payment rate disclosure would be required to be published consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. After publication of the 2011 proposed rule, and as we worked with States to implement the current AMRP requirements after publication of the 2015 final rule with comment period, many States expressed concerns that the current requirements of § 447.203, specifically those in current § 447.203(b)(6) that impose additional analysis and monitoring requirements in the case of provider rate reductions or restructurings that could result in diminished access, are overly burdensome. As described in the 2018 and 2019 proposed rules, "a number of States expressed concern regarding the administrative burden associated with the requirements of § 447.203, particularly those States with a very high beneficiary enrollment in comprehensive, risk-based managed care and a limited number of beneficiaries receiving care through a FFS delivery system." 188,189

Additionally, from our implementation experience, we learned that the triennial due date for updated AMRPs required by current § 447.203(b)(5)(ii) was too infrequent for States or CMS to identify and act on access concerns identified by the AMRPs. For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements in

188 83 FR 12696 at 12697.

^{189 84} FR 33722 at 33723.

§ 447.203(b)(1) through (5), and timely submitted its first AMRP update (the next ongoing AMRP) 3 years later, on October 1, 2019. The 2016 AMRP included data about beneficiary utilization and Medicaid-participating providers accepting new Medicaid patients from 2014 to 2015 (the most recent data available at the time the State was developing the AMRP), while the 2019 AMRP update included similar data for 2016 to 2017 (the most recent data then available). The 2019 AMRP showed that the number of Medicaid-participating providers accepting new Medicaid patients significantly dropped in 2016, and the State received a considerable number of public comments during the 30-day public comment period for the 2019 AMRP update prior to submission to us per the requirements in § 447.203(b) and (b)(2). This data lag between a drop in Medicaid-participating providers accepting new Medicaid patients in 2016 and CMS receiving the next AMRP update with information about related concerns in 2019 illustrates how the infrequency of the triennial due date for the AMRP updates could allow a potential access concern to develop without notice by the State or CMS in between the due dates of the ongoing AMRP updates. Although § 447.203(b)(7) currently requires States to have ongoing mechanisms for beneficiary and provider input on access to care, and States are expected to promptly respond to concerns expressed through these mechanisms that cite specific access problems, beneficiaries and providers themselves may not be aware of even widespread access issues if such issues are not noticed before published data reveal them.

We also learned from our AMRP implementation experience that the timing of the ongoing AMRP submissions required by current § 447.203(b)(5)(ii) and access reviews associated with rate reduction or restructuring SPA submissions required by § 447.203(b)(6) have led to confusion about the due date and scope of routine, ongoing AMRP updates and SPA-connected access review submissions, particularly when States were required to submit access reviews within the 3-year period between AMRP updates when proposing a rate reduction or restructuring SPA, per the requirements in current § 447.203(b)(6). For example, one State timely submitted its initial ongoing AMRP on October 1, 2016, consistent with the requirements

in § 447.203(b)(1) through (5), then the State submitted a SPA that proposed to reduce provider payment rates for physical therapy services with an effective date of July 1, 2018, along with an access review for the affected service completed within the prior 12 months, consistent with the requirements in § 447.203(b)(6). The State's access review submission consisted of its 2016 AMRP submission, updated with data from the 12 months prior to this SPA submission, with the addition of physical therapy services for which the SPA proposed to reduce rates. Because the State submitted an updated version of its 2016 AMRP in 2018 in support of the SPA submission, the State was confused whether its next AMRP update submission was due in 2019 (3 years from 2016), or in 2021 (3 years from 2018). Based on the infrequency of a triennial due date for AMRP updates and the numerous instances of similar State confusion during the implementation process for the AMRPs, we identified that the triennial timeframe was insufficient for the proposed comparative payment rate analysis and payment rate disclosure. As we considered a new timeframe for updates to the comparative payment rate analysis and payment rate disclosure to propose in this rulemaking, we initially considered proposing to require annual updates. However, we believe annual updates would add unnecessary administrative burden as annual updates would be too frequent because many States do not update their Medicaid fee schedule rates for the codes subject to the comparative payment rate analysis and payment rate disclosure on an annual basis.

As proposed, the payment rates for the categories of services subject to the proposed comparative payment rate analysis and payment rate disclosure are for office-based visits and, in our experience, the Medicaid payment rates generally do not change much over time due to the nature of an office visit. ¹⁹⁰ Office visits primarily include vitals being taken and the time a patient meets with a physician or NPP; therefore, States would likely have a considerable amount

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¹⁹⁰ We acknowledge that Medicaid primary care payment increase, a provision in the Patient Protection and Affordable Care Act (ACA, Pub. L. 111-148, as amended), temporarily raised Medicaid physician fees for evaluation and management services (Current Procedural Terminology codes 99201–99499) and vaccine administration services and counseling related to children's vaccines (Current Procedural Terminology codes 90460, 90461, and 90471–90474). This provision expired on December 31, 2014. https://www.macpac.gov/wp-content/uploads/2015/03/An-Update-on-the-Medicaid-Primary-Care-Payment-Increase.pdf.

of historical payment data for supporting the current payment rates for such services. Given the relatively stable nature of payment rates for office visits, we aim to help ensure the impact of the comparative payment rate analysis is maximized for ensuring compliance with section 1902(a)(30)(A) of the Act while minimizing unnecessary burden on States by holding all States to a proposed update frequency of 2 years to capture all Medicaid (and corresponding Medicare) payment rate changes.

As this proposed rule strives to reduce the amount of administrative burden from AMRPs on States while also fulfilling our oversight responsibilities, we believe updating the comparative payment rate analysis and payment rate disclosure no less than every 2 years achieves an appropriate balance between administrative burden and our oversight responsibilities with regard to section 1902(a)(30)(A) of the Act. We intend for the comparative payment rate analysis and payment rate disclosure States develop and publish to be time-sensitive and useful sources of information and analysis to help ensure compliance with section 1902(a)(30)(A) of the Act. If this proposal is finalized, both the comparative payment rate analysis and payment rate disclosure would provide the State, CMS, and other interested parties with cross-sectional data of Medicaid payment rates at various points in time. This data could be used to track Medicaid payment rates over time as a raw dollar amount and as a percentage of Medicare non-facility payment rates as listed on the Medicare PFS as well as changes in the number of Medicaid-paid claims volume and number of Medicaid enrolled beneficiaries who received a service over time. The availability of this data could be used to inform State policy changes, to compare payment rates across States, or be used for research on Medicaid payment rates and policies. While we believe the comparative payment rate analysis and payment rate disclosure would provide useful and actionable information to States, we do not want to overburden States with annual updates to the comparative payment rate analysis and payment rate disclosure. As we are proposing to replace the triennial AMRP process with less administratively burdensome processes (payment rate transparency publication, comparative payment rate analysis, payment rate disclosure, and

State analysis procedures for rate reductions and restructurings) for ensuring compliance with section 1902(a)(30)(A) of the Act, we believe annual updates to the comparative payment rate analysis and payment rate disclosure would negate at least a portion of the decrease in administrative burden from eliminating the AMRP process.

With careful consideration, we believe that our proposal to require updates to the comparative payment rate analysis and payment rate disclosure to occur no less than every 2 years is reasonable. We expect the proposed biennial publication requirement for the comparative payment rate analysis and payment rate disclosure after the initial publication date would be feasible for State agencies, provide a straightforward timeline for updates, limit unnecessary State burden, help ensure public payment rate transparency, and enable us to conduct required oversight. We are seeking public comment on the proposed timeframe for the initial publication and biennial update requirements for the comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(4).

Lastly, we also propose in paragraph (b)(4) to require States to publish the comparative payment rate analysis and payment rate disclosure consistent with the publication requirements described in proposed paragraph (b)(1) for payment rate transparency data. Paragraph (b)(1) would require the website developed and maintained by the single State Agency to be accessible to the general public. We are proposing States utilize the same website developed and maintained by the single State Agency to publish their Medicaid FFS payment rates and their comparative payment rate analysis and payment rate disclosure. We are seeking public comment on the proposed required location for States to publish their comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(4).

In § 447.203(b)(5), we propose a mechanism to ensure compliance with paragraphs (b)(1) through (b)(4). Specifically, we propose that, if a State fails to comply with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of proposed § 447.203, including requirements for the time and

manner of publication, that, under section 1904 of the Act and procedures set forth in regulations at 42 CFR part 430 subparts C and D, future grant awards may be reduced by the amount of FFP we estimate is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of proposed § 447.203 for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. We also propose that unless otherwise prohibited by law, FFP for deferred expenditures would be released after the State has fully complied with all applicable requirements. This proposed enforcement mechanism is similar in structure to the mechanism that applies with respect to the Medicaid Disproportionate Share Hospital (DSH) reporting requirements in § 447.299(e), which specifies that State failure to comply with reporting requirements will lead to future grant award reductions in the amount of FFP CMS estimates is attributable to expenditures made for payments to the DSH hospitals as to which the State has not reported properly. We are proposing this long-standing and effective enforcement mechanism in this proposed rule because we believe it is proportionate and clear, and to remain consistent with other compliance actions we take for State non-compliance with statutory and regulatory requirements. We are seeking public comment on the proposed method for ensuring compliance with the payment rate transparency and comparative payment rate analysis and payment rate disclosure requirements, as specified in proposed § 447.203(b)(5).

A fundamental element of ensuring access to covered services is the sufficiency of a provider network. As discussed elsewhere in this rule, the HCBS direct care workforce is currently experiencing notable worker shortages. ¹⁹¹ A robust workforce providing HCBS allows more beneficiaries to obtain necessary services in home and community-based settings. We are proposing to use data-driven benchmarks in requiring comparative payment rate analyses relative to Medicare non-facility payment rates for the categories of service specified in proposed § 447.203(b)(2)(i) through (iii), but Medicare non-facility payment rates are generally not

191 https://www.macpac.gov/wp-content/uploads/2022/03/MACPAC-brief-on-HCBS-workforce.pdf.

relevant in the context of HCBS, as discussed earlier in this section. Furthermore, data alone cannot replace the lived experience of direct care workers and recipients of the services they provide.

Understanding how Medicaid payment rates compare in different geographic areas of a State and across State programs is also an important access to care data point for covered benefits where Medicaid is a predominant payer of services, as in the case of HCBS. In the absence of HCBS coverage and a lack of available payment rate and claims utilization data from other health payers, such as Medicare or private insurers, and with the significant burden and potential infeasibility associated with gathering payment data for individuals who pay out of pocket (that is, self-pay), we believe it would be a reasonable standard for States to compare their rates to geographically similar State Medicaid program payment rates as a basis for understanding compliance with section 1902(a)(30)(A) of the Act for those services. In addition, even for services where other payers establish payment rates, comparisons to rates paid by other geographically similar States could be important to understanding compliance with section 1902(a)(30)(A) of the Act since Medicaid beneficiaries may have unique health care needs that are not typical of the general population in particular geographic areas.

Section 2402(a) of the Affordable Care Act directs the Secretary to promulgate regulations ensuring that all States develop service systems that, among other things, improve coordination and regulation of providers of HCBS to oversee and monitor functions, including a complaint system, and ensure that there are an adequate number of qualified direct care workers to provide self-directed services. This statutory mandate, coupled with the workforce shortages exacerbated by the COVID-19 pandemic, necessitates action specific to direct care workers. As such, we are proposing to require States to establish an interested parties' advisory group to advise and consult on FFS rates paid to direct care workers providing self-directed and agency-directed HCBS, at a minimum for personal care, home health aide, and homemaker services as described in § 440.180(b)(2) through (4), and States may choose to include other HCBS. The

definition of direct care workers is proposed elsewhere in this rule under § 441.302(k)(1)(ii). We propose to utilize that definition, to consider a direct care worker a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving HCBS; a licensed nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist; a direct support professional; a personal care attendant; a home health aide; or other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living directly to Medicaid-eligible individuals receiving HCBS available under part 441, subpart G. A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.

We propose that the group would consult on rates for service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to individual providers or providers employed by an agency for, at a minimum, the previously described types of services, including for personal care, home health aide, and homemaker services provided under sections 1905(a), 1915(i), 1915(j), and 1915(k) State plan authorities, and section 1915(c) waivers. These proposed requirements also would extend to rates for HCBS provided under section 1115 demonstrations, as is typical for rules pertaining to HCBS authorized using demonstration authority. The interested parties advisory group may consult on other HCBS, at the State's discretion.

Specifically, in § 447.203(b)(6), we propose that the State agency would be required to establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, section 1915(c) waiver and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.302(k)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4). The interested parties' advisory group would be required to

include, at a minimum, direct care workers, beneficiaries and their authorized representatives, and other interested parties. "Authorized representatives" refers to individuals authorized to act on the behalf of the beneficiary, and other interested parties may include beneficiary family members and advocacy organizations. To the extent a State's MAC established under proposed § 431.12, if finalized, meets the requirements of this regulation, the State could utilize that committee for this purpose. However, we note the roles of the MAC under proposed § 431.12 and the interested party advisory group under proposed § 447.203(b)(6) would be distinct, and the existence or absence of one committee or group (for example, if one of these proposals is not finalized) would not affect the requirements with respect to the other as established in a final rule.

We further propose in § 447.203(b)(6)(iii) that the interested parties' advisory group would advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are sufficient to ensure access to homemaker services, home health aide services, and personal care services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

In proposed § 447.203(b)(6)(iv), we propose that the interested parties advisory group would meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency would be required to ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics for HCBS as described in § 441.311(d)(2) to produce these recommendations. These materials would be required to be made be available with sufficient time for the advisory group to consider them,

formulate recommendations, and transmit those recommendations to the State. If the State has asked the group to consider a proposed rate change, they would need to provide the group with sufficient time to review and produce a recommendation within the State's intended rate adjustment schedule. This would be necessary because the group's recommendation would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze. The interested parties' advisory group would make recommendations to the Medicaid agency on the sufficiency of the established and proposed State plan, section 1915(c) waiver and demonstration payment rates, as applicable. In other words, the group would provide information to the State regarding whether, based on the group's knowledge and experience, current payment rates are sufficient to enlist a sufficiently large work force to ensure beneficiary access to services, and whether a proposed rate change would be consistent with a sufficiently large work force or would disincentivize participation in the work force in a manner that might compromise beneficiary access.

We propose to require States to convene this interested parties' advisory group every 2 years, at a minimum, to advise and consult on current and suggested payment rates and the sufficiency of these rates to ensure access to HCBS for beneficiaries consistent with section 1902(a)(30)(A) of the Act. This timing aligns with the comparative payment rate analysis and payment rate disclosure publication requirements proposed in § 447.203(b)(4), although we note that this would be a minimum requirement and a State may find that more frequent meetings would be necessary or helpful for the advisory group to provide meaningful and actionable feedback. We further propose that the process by which the State selects its advisory group members and convenes meetings would be required to be made publicly available, but other matters, such as the tenure of members, would be left to the State's discretion.

Finally, in § 447.203(b)(6)(v), we propose that the Medicaid agency would be required to publish the recommendations of the interested parties' advisory group consistent with the

publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency. We intend that States would consider, but not be required to adopt, the recommendations of the advisory group. Under this proposal, the work of the advisory group would be regarded as an element of the State's overall rate-setting process. Additionally, the feedback of this advisory group would not be required for rate changes. That is to say, should a State need or want to adjust rates and it is not feasible to obtain a recommendation from the advisory group in a particular instance, the State would still be permitted to submit its rate change SPA to CMS. However, to the extent the group comments on proposed rate changes, its feedback would be considered part of the interested parties input described in proposed §§ 447.203(c)(4) and 447.204(b)(3), which States would be required to consider and analyze, and submit such analysis to us, in connection with any SPA submission that proposes to reduce or restructure Medicaid service payment rates. In addition, by way of clarification, we intend that the advisory group would be permitted to suggest alternate rates besides those proposed by the State for consideration.

We are seeking public comment on the proposed interested parties advisory group and about whether other categories of services should be included in the requirement for States to consult with the interested parties advisory group.

3. State Analysis Procedures for Rate Reduction or Restructuring (§ 447.203(c))

As stated previously, the Supreme Court's Armstrong decision underscored the importance of CMS' administrative review of Medicaid payment rates to ensure compliance with section 1902(a)(30)(A) of the Act. CMS' oversight role is particularly important when States propose to reduce provider payment rates or restructure provider payments, since provider payment rates can affect provider participation in Medicaid, and therefore, beneficiary access to care. In § 447.203(c), we propose a process for State access analyses that would be required

whenever a State submits a SPA proposing to reduce provider payment rates or restructure provider payments.

As noted previously, the 2015 final rule with comment period required that, for any SPA proposing to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, States must submit a detailed analysis of access to care under $\S\S$ 447.203(b)(1) and (b)(6) and 447.204(b)(1). This analysis includes, under current § 447.203(b)(1), the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. Currently, this information is required for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, regardless of the provider payment rates or levels of access to care before the proposed reduction or restructuring.

Following the implementation of the 2015 final rule with comment period, as we worked with States to implement the AMRP requirements, many States expressed concerns that the requirements that accompany proposed rate reductions or restructurings are overly burdensome. Specifically, States pointed to instances where proposed reductions or restructurings are nominal, or where rate changes are made via the application of a previously approved rate methodology, such as when the State's approved rate methodology ties Medicaid payment rates to a Medicare fee schedule and the Medicare payment rate is reduced. We acknowledged these concerns through previous proposed rulemaking. In the 2018 proposed rule, we agreed that our experience implementing the AMRP process from the 2015 final rule with comment period

raised questions about the benefit of the access analysis when proposed rate changes include nominal rate reductions or restructurings that are unlikely to result in diminished access to care. 192

We did not finalize the 2018 proposed rule; instead, in response to feedback, we proposed a rescission of the AMRP process in the 2019 proposed rule. ¹⁹³ In that proposed rule, we indicated that future guidance would be forthcoming to provide information on the required data and analysis that States might submit with rate reduction or restructuring SPAs in place of the AMRPs to support compliance with section 1902(a)(30)(A) of the Act. ¹⁹⁴ We did not finalize the rescission proposed in the 2019 proposed rule. Although we are concerned that the current AMRP process is overly burdensome for States and CMS in relation to the benefit obtained in helping ensure compliance with the access requirement in section 1902(a)(30)(A) of the Act, our 2018 and 2019 proposed rules did not adequately consider our need for information and analysis from States seeking to reduce provider payment rates or restructure provider payments to enable us to determine that the statutory access requirement is met when making SPA approval decisions.

To improve the efficiency of our administrative procedures and better inform our SPA approval decisions, this proposed rule would establish standard information that States would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when the changes could result in diminished access, including a streamlined set of data when the reductions or restructurings are nominal, the State rates are above a certain percentage of Medicare payment rates, and there are no evident access concerns raised through public processes; and an additional set of data elements that would be required when States propose FFS provider payment rate reductions or restructurings in circumstances when the changes could result in diminished access and these criteria are not met. For both sets of

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¹⁹² 83 FR 12696 at 12697.

^{193 84} FR 3372.2

¹⁹⁴ Id at 33723.

required or potentially required elements, we are proposing to standardize the data and information States would be required to submit with rate reduction or restructuring SPAs.

Although the AMRP processes have helped to improve our administrative reviews and helped us make informed SPA approval determinations, the procedures within this proposed rule would provide us with similar information in a manner that reduces State burden. Additionally, the proposed procedures would provide States increased flexibility to make program changes with submission of streamlined supporting data to us when current Medicaid rates and proposed changes fall within specified criteria that create a reasonable presumption that proposed reductions or restructuring would not reduce beneficiary access to care in a manner inconsistent with section 1902(a)(30)(A) of the Act.

This proposed rule seeks to achieve a more appropriate balance between reducing unnecessary burden for States and CMS, and ensuring that we have the information necessary to make appropriate determinations for whether a rate reduction or restructuring SPA might result in beneficiary access to covered services failing to meet the standard in section 1902(a)(30)(A) of the Act. In § 447.203(c), we propose to establish analyses that States would be required to perform, document, and submit concurrently with the submission of rate reduction and rate restructuring SPAs, with additional analyses required in certain circumstances due to potentially increased access to care concerns.

We are proposing a two-tiered approach for determining the level of access analysis States would be required to conduct when proposing provider payment rate reductions or payment restructurings. The first tier of this approach, proposed at § 447.203(c)(1), sets out three criteria for States to meet when proposing payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access that, if met, would not require a more detailed analysis to establish that the proposal meets the access requirement in section 1902(a)(30)(A) of the Act. The State agency would be required to provide written assurance and relevant supporting documentation that the three criteria specified

in those paragraphs are met, as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act. As explained in more detail later in this section, these criteria proposed in § 447.203(c)(1) represent thresholds we believe would likely assure that Medicaid payment rates would continue to be sufficient following the change to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

We note that, in the course of our review of a payment SPA that meets these criteria, as with any SPA review, we may need to request additional information to ensure that all Federal SPA requirements are met. We also note that meeting the three criteria described in proposed § 447.203(c)(1) does not guarantee that the SPA would be approved, if other applicable Federal requirements are not met. Furthermore, if any criterion in the first tier is not met, we propose a second tier in § 447.203(c)(2), which would require the State to conduct a more extensive access analysis in addition to providing the results of the analysis in the first tier. A detailed discussion of the second tier follows the details of the first tier in this section.

Under proposed § 447.203(c)(1)(i), the State would be required to provide a supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

In proposed § 447.203(c)(1)(i), we mean for "benefit category" to refer to all individual services under a category of services described in section 1905(a) of the Act for which the State is proposing a payment rate reduction or restructuring. Comparing the payment rates in the aggregate would involve first performing a comparison of the Medicaid to the Medicare payment rate on a code-by-code basis, meaning CPT, CDT, or HCPCS as applicable, to derive a ratio for individual constituent services, and then the ratios for all codes within the benefit category would

be averaged by summing the individual ratios then dividing the sum by the number of ratios. For example, if the State is seeking to reduce payment rates for a subset of physician services, the State would review all current payment rates for all physician services and determine if the proposed reduction to the relevant subset of codes would result in an average Medicaid payment rate for all physician services that is at or above 80 percent of the average corresponding Medicare payment rates. For supplemental payments, we are relying upon the definition of supplemental payments in section 1903(bb)(2) of the Act, which defines supplemental payments as "a payment to a provider that is in addition to any base payment made to the provider under the State plan under this title or under demonstration authority . . . [b]ut such term does not include a disproportionate share hospital payment made under section 1923 [of the Act]." With the inclusion of supplemental payments, States would need to aggregate the supplemental payments paid to qualifying providers during the State fiscal year and divide by all providers' total service volume (including service volume of providers that do not qualify for the supplemental payment) to establish an aggregate, per-service supplemental payment amount, then add that amount to the State's fee schedule rate to compare the aggregate Medicaid payment rate to the corresponding Medicare payment rate. As this supportive assurance in proposed § 447.203(c)(1)(i) is expected to be provided with an accompanying SPA, CMS may ask the State to explain how the analysis was conducted if additional information is needed as part of the analysis of the SPA. We are requesting comment on the proposed § 447.203(c)(1)(i) supported assurance that Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services should include a weighted average of the payment rate analysis by service volume, number of beneficiaries receiving the service, and total amount paid by Medicaid for the code in

a year using State's Medicaid utilization data from the MMIS claims system rather than using a straight code-by-code analysis.

We understand that this approach may have a smoothing effect on the demonstrated overall levels of Medicaid payment within a benefit category under the State plan. In many circumstances, only a subset of providers are recipients of Medicaid supplemental payments with the rest of the providers within the benefit category simply receiving the State plan fee schedule amount. This could result in a demonstration showing the Medicaid payments being high relative to Medicare, but the actual payments to a large portion of the providers would be less than the overall demonstration would suggest. As an alternative, we considered whether to adopt separate comparisons for providers who do and who do not receive supplemental payments, where a State makes supplemental payments for a service to some but not all providers of that service. We are requesting comments on the proposed approach and this alternative.

We selected FFS Medicare, as opposed to Medicare Advantage, as the proposed payer for comparison for a number of reasons. A threshold issue is payment rate data availability: private payer data may be proprietary or otherwise limited in its availability for use by States. In addition, Medicare sets its prices rather than negotiating them through contracts with providers, and is held to many similar statutory standards as Medicaid with respect to those prices, such as efficiency, access, and quality. For example, section 1848(g)(7) of the Act directs the Secretary of HHS to monitor utilization and access for Medicare beneficiaries provided through the Medicare fee schedule rates, and directs that the Medicare Payment Advisory Commission (MedPAC) shall comment on the Secretary's recommendations. In developing its comments, MedPAC convenes and consults a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care. In a March 2001 report, MedPAC summarized its evaluation of Medicare rates, stating "Medicare buys health care

 $^{^{195}\} https://www.healthcarevaluehub.org/advocate-resources/publications/medicare-rates-benchmark-too-much-too-little-or-just-right.$

products and services from providers who compete for resources in private markets. To ensure beneficiaries' access to high-quality care, Medicare's payment systems therefore must set payment rates for health care products and services that are: high enough to stimulate adequate numbers of providers to offer services to beneficiaries, sufficient to enable efficient providers to supply high-quality services, given the trade-offs between cost and quality that exist with current technology and local supply conditions for labor and capital, and low enough to avoid imposing unnecessary burdens on taxpayers and beneficiaries through the taxes and premiums they pay to finance program spending." Medicare's programmatic focus on beneficiary access aligns with the requirements of section 1902(a)(30)(A) of the Act.

In addition, Medicare fee schedule rates are stratified by geographic areas within the States, which we seek to consider, as well to ensure that payment rates are consistent with section 1902(a)(30)(A) of the Act. The Medicare PFS pricing amounts are adjusted to reflect the variation in practice costs from area to area. Medicare established GPCI for every Medicare payment locality for each of the three components of a procedure's relative value unit (that is, the RVUs for work, practice expense, and malpractice). The current Medicare PFS locality structure was implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). Under the current locality structure, there are 112 total PFS localities.¹⁹⁷

When considering geography in their rate analyses, CMS expects States to conduct a code-by-code analysis of the ratios of Medicaid-to-Medicare provider payment rates for all applicable codes within the benefit category, either for each of the GPCIs within the State, or by

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¹⁹⁶ MedPAC. Report to the Congress: Medicare Payment Policy, March 2001. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar01Ch1.pdf. Accessed December 20, 2022.

197 Section 220(b) of PAMA 204 added section 1848(e)(6) of the Act, which requires that, for services furnished on or after January 1, 2017, the locality definitions for California, which has the most unique locality structure, be based on the Metropolitan Statistical Area (MSA) delineations as defined by the Office of Management and Budget (OMB). The resulting modifications to California's locality structure increased its number of localities from 9 under the previous structure to 27 under the MSA-based locality structure (operational note: for the purposes of payment the actual number of localities under the MSA-based locality structure is 32). Of the 112 total PFS localities, 34 localities are Statewide areas (that is, only one locality for the entire State). There are 75 localities in the other 16 States, with 10 States having 2 localities, 2 States having 3 localities, 1 State having 4 localities, and 3 States having 5 or more localities. The District of Columbia, Maryland, and Virginia suburbs, Puerto Rico, and the Virgin Islands are additional localities that make up the remainder of the total of 112 localities. Medicare PFS Locality Configuration. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality. Accessed December 21, 2022.

calculating an average Medicare rate across the GPCIs within the State (such as in cases where a State does not vary its rates by region). In cases where a State does vary its Medicaid rates based on geography, but that variation does not align with the Medicare GPCI, the State should utilize the Medicare payment rates as published by Medicare for the same geographical location as the Medicaid base payment rates to achieve an equivalent comparison and align the Medicare GPCI to the locality of the Medicaid payment rates, using the county and locality information provided by Medicare for the GPCIs, for purposes of creating a reasonable comparison of the payment rates. ¹⁹⁸ To conduct such an analysis that meets the requirements of proposed § 447.203(c)(1)(i), States may compare the Medicaid payment rates applicable to the same Medicare GPCI to each Medicare rate by GPCI individually, and then aggregate that comparison into an average rate comparison for the benefit category. To the extent that Medicaid payment rates do not vary by geographic locality within the State, the State may also calculate a Statewide average Medicare rate based upon all of the rates applicable to the GPCIs within that State, and compare that average Medicare rate to the average Medicaid rate for the benefit category.

Once we decided to propose using Medicare payment rates as a point of comparison, we needed to decide what threshold ratio of proposed Medicaid to Medicare payment rates should trigger additional consideration and review for potential access issues. First, we considered how current levels of Medicaid payment compares to the Medicare payment for the same services. In a 2021 *Health Affairs* article, Zuckerman, et al, found that "Medicaid physician fees were 72 percent of Medicare physician fees for twenty-seven common procedures in 2019." This ratio varied by service type. For example, "the 2019 Medicaid-to-Medicare fee index was lower for primary care (0.67) than for obstetric care (0.80) or for other services (0.78)." The authors also

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¹⁹⁸ https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Locality.

¹⁹⁹ Zuckerman, S. et al. "Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019," Health Affairs, Volume 40, Number 2, February 2021. Available at https://doi.org/10.1377/hlthaff.2020.00611 (accessed December 23, 2022).

found that "between 2008 and 2019 Medicare and Medicaid fees both increased (23.6 percent for Medicare fees and 19.9 percent for Medicaid fees), leaving the fee ratios similar." ²⁰⁰

Next, considering that Medicaid rates are generally lower than Medicare, we wanted to examine the relationship between these rates and a beneficiary's ability to access covered services. This led us to first look into a comparison of physician new patient acceptance rates based on a prospective new patient's payer. In a June 2021 fact sheet, the Medicaid and CHIP Payment and Access Commission (MACPAC) found "in 2017 (the most recent year available), physicians were significantly less likely to accept new patients insured by Medicaid (74.3 percent) than those with Medicare (87.8 percent) or private insurance (96.1 percent)."²⁰¹ MACPAC found this to be true "regardless of physician demographic characteristics (age, sex, region of the country); and type and size of practice."²⁰²

We then wanted to confirm whether this was related to the rates themselves. In a 2019 *Health Affairs* article, the authors found that, "higher payment continues to be associated with higher rates of accepting new Medicaid patients...physicians most commonly point to low payment as the main reason they choose not to accept patients insured by Medicaid."²⁰³ The study found that physicians in States that pay above the median Medicaid-to-Medicare fee ratio accepted new Medicaid patients at higher rates than those in States that pay below the median, with acceptance rates increasing by nearly 1 percentage point (0.78) for every percentage point increase in the fee ratio.²⁰⁴

Similarly, in a 2020 study published by the *National Bureau of Economic Research*, researchers found that there was a positive association between increasing Medicaid physician fees and increased likelihood of having a usual source of care, improved access to specialty

²⁰⁰ Id

²⁰¹ MACPAC. "Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey." June. 2021. Available at https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf (accessed December 23, 2023).

²⁰² Id.

²⁰³ Holgash, K. and Martha Heberlein, "Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't." *Health Affairs*, April 10, 2019. Available at https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/ (accessed February 22, 2023).

doctor care, and large improvements in caregivers' satisfaction with the adequacy of health coverage, among children with special health care needs with a public source of health coverage.²⁰⁵ Further, Berman, et al, focused on pediatricians looked at Medicaid-Medicare fee ratio quartiles and found that the percent of pediatricians accepting all Medicaid patients and relative pediatrician participation in Medicaid increased at each quartile, but improvement was most significant up to the third quartile.²⁰⁶ According to the Kaiser Family Foundation, in 2016, following the expiration of section 1202 of the Affordable Care Act (Pub. L. 111-148), which amended section 1902(a)(13) of the Act to implement a temporary payment floor for certain Medicaid primary care physician services, the third quartile of States had Medicaid-Medicare fee ratios of between 79 and 86 percent for all services provided under all State Medicaid fee-forservice programs.²⁰⁷ Importantly, considering the proposed requirements at paragraph (c) pertain to proposed payment rate reductions or payment restructurings in circumstances when the changes could result in diminished access, multiple recent studies have also shown that the association between Medicaid physician fees and measures of beneficiary access are consistent whether physician payments are increased or decreased to reach a particular level at which access is assessed.²⁰⁸

The Kaiser Family Foundation found that 23 States have Medicaid-to-Medicare fee ratios of at least 80 percent for all services, 17 States have fee ratios of 80 percent for primary care services, 32 States have fee ratios of 80 percent for obstetric care, and 27 States have fee ratios of 80 percent for other services. Additional studies support the Holgash and Heberlein findings that physicians most commonly point to low payment as the main reason they choose not to

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²⁰⁵ Chatterji, P. et al. "Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs" National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2-54. Medicaid Physician Fees and Access to Care among Children with Special Health Care Needs | NBER. Accessed June 16, 2022.

²⁰⁶ Berman, S., et al. "Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients" *Pediatrics*.

²⁰⁷ https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.

²⁰⁸ Candon, M., et al. "Declining Medicaid Fees and Primary Care Appointment Availability for New Medicaid Patients" *JAMA Internal Medicine*, Volume 178, Number 1, January 2018, p. 145-146. Available at https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2663253. Accessed June 16, 2022.

²⁰⁹ https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.

accept patients insured by Medicaid, showing that States with a Medicaid to Medicare fee ratio at or above 80 percent show improved access for children to a regular source of care, ²¹⁰ and decreased use of hospital-based facilities, versus States with a lower Medicaid to Medicare fee ratio.

In general, we are concerned that higher rates of acceptance by some providers of new patients with payers other than Medicaid (specifically, Medicare and private coverage), and indications by some providers that low Medicaid payments are a primary reason for not accepting new Medicaid patients, may suggest that some beneficiaries could have a more difficult time accessing covered services than other individuals in the same geographic area. We are encouraged by findings that suggest that some increases in Medicaid payment rates may drive increases in provider acceptance of new Medicaid patients, with one study finding that new Medicaid patient acceptance rates increased by 0.78 percent for every percentage point increase in the Medicaid-to-Medicare fee ratio, for certain providers for certain States above the median Medicaid-to-Medicare fee ratio.²¹¹ In line with the Berman study, which found that increases in the percentage of pediatricians participating in Medicaid and of pediatricians accepting new Medicaid patients occurred with Medicaid payment rate increases at each quartile of the Medicaid-to-Medicare fee ratio but were most significant up to the third quartile, we believe that beneficiaries in States that provide this level of Medicaid payment generally may be less likely to encounter access to care issues at rates higher than the general population.²¹³ In line with the Kaiser Family Foundation reporting of the Medicaid-to-Medicare fee ratio third quartile as ranging from 79 to 86 percent in 2016, depending on the service, we believe that a minimum

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²¹⁰ Chatterji, P. et al. "Medicaid Physician Fees and Access to Care Among Children with Special Health Care Needs" National Bureau of Economic Research, Working Paper 26769, February 2020, p. 2-54. Available at https://www.nber.org/papers/w26769, Accessed August 16, 2022.

²¹¹ MACPAC. "Physician Acceptance of New Medicaid Patients: Finding from the National Electronic Health Records Survey." June. 2021. Available at https://www.macpac.gov/wp-content/uploads/2021/06/Physician-Acceptance-of-New-Medicaid-Patients-Findings-from-the-National-Electronic-Health-Records-Survey.pdf (accessed December 23, 2023).

²¹² Holgash, K. and Martha Heberlein, "Physician Acceptance Of New Medicaid Patients: What Matters And What Doesn't." *Health Affairs*, April 10, 2019. Available at https://www.healthaffairs.org/do/10.1377/forefront.20190401.678690/full/ (accessed February 22, 2023).

²¹³ Berman, S., et al. "Factors that Influence the Willingness of Private Primary Care Pediatricians to Accept More Medicaid Patients" *Pediatrics*.

80 percent Medicaid-to-Medicare fee ratio is a reasonable threshold to propose in § 447.203(c)(1)(i) as one of three criteria State proposals to reduce or restructure provider payments would be required to meet to qualify for the proposed streamlined documentation process.²¹⁴ As documented by the Kaiser Family Foundation, many States currently satisfy this ratio for many Medicaid-covered services, and according to findings by Zuckerman, et al. in Health Affairs, in 2019, the average nationwide fee ratio for obstetric care met this proposed threshold.²¹⁵ ²¹⁶ We propose that this percentage would hold across benefit categories, because we did not find any indication that a lower threshold would be adequate, or that a higher threshold would be strictly necessary, to support a level of access to covered services for Medicaid beneficiaries at least as great as for the general population in the geographic area. It is worth noting that the disparities in provider participation for some provider types may be larger than this overview suggests, as such we are proposing a uniform standard in the interest of administrative simplicity, but note that States must meet all three of the criterion in proposed paragraph (c)(1) to qualify for the streamlined analysis process; otherwise, the additional analysis specified in proposed paragraph (c)(2) would be required.

Given the results of this literature review, and by proposing this provision as only one part of a three-part assessment of the likely effect of a proposed payment rate reduction or payment restructuring on access to care, as further discussed in this section, we propose 80 percent of the most recently published Medicare payment rates, as identified on the applicable Medicare fee schedule for the same or a comparable set of Medicare-covered services, as a benchmark for the level of Medicaid payment for benefit categories that are subject to proposed provider payment reductions or restructurings that is likely to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent as to the general

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²¹⁴ https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index.

²¹⁵ Id

²¹⁶ Zuckerman, S. et al. "Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019," Health Affairs, Volume 40, Number 2, February 2021. Available at https://doi.org/10.1377/hlthaff.2020.00611 (accessed December 23, 2022).

population in the geographic area, where the additional tests in proposed § 447.203(c)(1) also are met. The published Medicare payment rates means the amount per applicable procedure code identified on the Medicare fee schedule. The established Medicare fee schedule rate includes the amount that Medicare pays for the claim and any applicable co-insurance and deductible amounts owed by the patient. Medicaid fee-schedule rates should be representative of the total computable payment amount a provider would expect to receive as payment-in-full for the provision of Medicaid services to individual beneficiaries. Section 447.15 defines payment-in-full as "the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual." Therefore, State fee schedule should be inclusive of total base payment from the Medicaid agency plus any applicable coinsurance and deductibles to the extent that a beneficiary is expected to be liable for those payments. If a State Medicaid fee schedule does not include these additional beneficiary cost-sharing payment amounts, then the Medicaid fee schedule amounts would need to be modified to include expected beneficiary cost sharing to align with Medicare's fee schedule.

We note that Medicaid benefits that do not have a reasonably comparable Medicarecovered analogue, and for which a State proposes a payment rate reduction or payment
restructuring in circumstances when the changes could result in diminished access, would be
subject to the expanded review criteria proposed in § 447.203(c)(2), because the State would be
unable to demonstrate its Medicaid payment rates are at or above 80 percent of Medicare
payment rates for the same or a comparable set of Medicare-covered services after the payment
rate reduction or payment restructuring in circumstances when the changes could result in
diminished access. For identifying a comparable set of Medicare-covered services, we would
expect to see services that bear a reasonable relationship to each other. For example, the clinic
benefit in Medicaid does not have a directly analogous clinic benefit in Medicare. In Medicaid,
clinic services generally are defined in § 440.90, as "preventive, diagnostic, therapeutic,
rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital

but is organized and operated to provide medical care to outpatients." This can include a number of primary care services otherwise available through physician practices and other primary care providers, such as nurse practitioners. Therefore, in seeking to construct a comparable set of Medicare-covered services to which the State could compare its proposed Medicaid payment rates, the State reasonably could include Medicare payment rates for practitioner services, such as physician and nurse practitioner services, or payments for facility-based services that bear a reasonable similarity to clinic services, potentially including those provided in Ambulatory Surgical Centers. We would expect the State to develop a reasonably comparable set of Medicare-covered services to which its proposed Medicaid payment rates could be compared and to include with its submission an explanation of its reasoning and methodology for constructing the Medicare rate to compare Medicaid payment rates to.

In § 447.203(c)(1)(ii), we propose that the State would be required to provide a supported assurance that the proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the State fiscal year, would result in no more than a 4 percent reduction in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a single State fiscal year. The documentation would need to show the change stated as a percentage reduction in aggregate FFS Medicaid expenditures for each affected benefit category. We recognize that the effects of payment rate reductions and payment restructurings on beneficiary access generally cannot be determined through any single measure, and applying a 4 percent threshold without sufficient additional safeguards would not be prudent. Therefore, we are proposing to limit the 4 percent threshold as the cumulative percentage of rate reductions or restructurings applied to the overall FFS Medicaid expenditures for a particular benefit category affected by the proposed reduction(s) or restructuring(s) within each State fiscal year. We are proposing the cumulative application of the threshold to State plan actions taken within a State fiscal year as opposed to a SPA-specific application to avoid circumstances where a State may propose rate reductions or restructurings

that cumulatively exceed the 4 percent threshold across multiple SPAs without providing additional analysis.

For example, if a State proposed to reduce payment rates for a broad set of obstetric services by 3 percent in State fiscal year 2023 and had not proposed any other payment changes affecting the benefit category of obstetric care during the same State fiscal year, that payment change would meet the criterion proposed in § 447.203(c)(1)(ii) because it would be expected to result in no more than a 3 percent reduction in aggregate Medicaid expenditures for obstetric care within a State fiscal year. However, if the State had received approval earlier in the State fiscal year to revise its obstetric care payment methodology to include value-based arrangements expected to reduce overall Medicaid expenditures for obstetric care by 2 percent per State fiscal year, then it is likely that the cumulative effect of the proposal to reduce payment rates for a broad set of obstetric services by 3 percent and the Medicaid obstetric care expenditure reductions under the earlier-approved payment restructuring would result in an aggregate reduction to FFS Medicaid expenditures for obstetric services of more than 4 percent in a State fiscal year. If so, the State's proposal would not meet the criterion proposed in § 447.203(c)(1)(ii), and the proposal would be subject to the additional review criteria proposed in § 447.203(c)(2). The State would need to document for our review whether the three percent payment rate reduction proposal for the particular subset of obstetric services would be likely to result in a greater than 2 percent further reduction in aggregate FFS Medicaid expenditures for obstetric care as compared to the expected expenditures for such services for the State fiscal year before any payment rate reduction or payment restructuring; if this expected aggregate reduction is demonstrated to be 2 percent or less, then the proposal still could meet the criterion proposed in § 447.203(c)(1)(ii).

We propose to codify a 4 percent reduction threshold for aggregate FFS Medicaid expenditures in each benefit category affected by a proposed payment rate reduction or payment restructuring within a State fiscal year. This threshold is consistent with one we proposed in the

2018 proposed rule, which proposed to require the States to submit an AMRP with any SPA that proposed to reduce provider payments by greater than 4 percent in overall service category spending in a State fiscal year or greater than 6 percent across 2 consecutive State fiscal years, or restructure provider payments in circumstances when the changes could result in diminished access.²¹⁷ The proposed rule received positive feedback from States regarding its potential for mitigating administrative burden, and providing States with flexibility to administer their programs and make provider payment rate changes. Some States and national organizations requested that we increase the rate reduction threshold to 5 percent and increase the consecutive year threshold to 8 percent.^{218, 219} Non-State commenters cautioned CMS against providing too much administrative flexibility and to not abandon the Medicaid access analysis the current regulations require. Commenters also raised that 4 and 6 percent may seem nominal for larger medical practices and health care settings, but for certain physician practices or direct care workers a 6 percent reduction in payment could be considerable.²²⁰ This feedback has been essential in considering how we proceed with this proposed rule, in which we emphasize that the size of the rate reduction threshold proposed in § 447.203(c)(1)(ii) would operate in conjunction with the two other proposed elements in § 447.203(c)(1)(i) and (iii) to qualify the State for a streamlined analysis process and would not exempt the proposal from scrutiny for compliance with section 1902(a)(30)(A) of the Act.

We are proposing a 4 percent threshold on cumulative provider payment rate reductions throughout a single State fiscal year as one of the criteria of the streamlined process in proposed paragraph (c)(1), and therefore, emphasizing that while we believe this payment threshold to be nominal and unlikely to diminish access to care, we propose to include paragraph (c)(1)(i) to

²¹⁷ 83 FR 12696 at 12698.

²¹⁸ Connecticut Department of Social Services. Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0021/attachment 1.pdf.

²¹⁹ National Association of Medicaid Directors. Comment Letter on 2018 Proposed rule (June 1, 2018), https://downloads.regulations.gov/CMS-2018-0031-0115/attachment 1.pdf.

²²⁰ American Academy of Family Physicians, Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0017/attachment 1.pdf.

require States to review current levels of provider payment in relation to Medicare and propose to include paragraph (c)(1)(iii) to require that States rely on the public process to inform the determination on the sufficiency of the proposed payment rates after reduction or restructuring, with consideration for providers and practice types that may be disproportionately impacted by the State's proposed rate reductions or restructurings.

As previously noted, we would not consider any payment rate reduction or payment rate restructuring proposal to qualify for the streamlined analysis process in the proposed paragraph (c)(1) unless all three of the proposed paragraph (c)(1) criteria are met. Using information from the Kaiser Family Foundation's Medicaid-to-Medicare fee index²²¹ as an example, only 15 States could have reduced primary care service provider payment rates by up to 4 percent in 2019 and continued to meet the 80 percent of Medicare threshold in proposed paragraph (c)(1). Even those 15 States with rates above the 80 percent of Medicare threshold would be subject to proposed paragraph (c)(2) requirements if the State received significant public feedback that the proposed payment reduction or restructuring would result in an access to care concern, if the State were unable to reasonably respond to or mitigate such concerns. All States with primary care service payment rates below the 80 percent of Medicare threshold, no matter the size of the payment rate reduction or restructuring and no matter whether interested parties expressed access concerns through available public processes, would have to conduct an additional access analysis required under proposed paragraph (c)(2).

We issued SMDL #17-004 to provide States with guidance on complying with regulatory requirements to help States avoid unnecessary burden when seeking approval of and implementing payment changes, because States often seek to make payment rate and/or payment structure changes for a variety of programmatic and budgetary reasons with limited or potentially no effect on beneficiary access to care, and we recognized that State legislatures needed some flexibility to manage State budgets accordingly. We discussed a 4 percent spending reduction

²²¹ https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/.

threshold with respect to a particular service category in SMDL #17-004 as an example of a targeted reduction where the overall change in net payments within the service category would be nominal and any effect on access difficult to determine (although we reminded States that they should document that the State followed the public process under § 447.204, which could identify access concerns even with a seemingly nominal payment rate reduction). To our knowledge, since the release of SMDL #17-004, the 4 percent threshold for regarding a payment rate reduction as nominal has not resulted in access to care concerns in State Medicaid programs, and it received significant State support for this reason in comments submitted in response to the 2018 proposed rule.²²²

In instances where States submitted payment rate reduction SPAs after the publication of SMDL #17-004, we routinely have asked the State for an explanation of the purpose of the proposed change, whether the FFS Medicaid expenditure impact for the service category would be within a 4 percent reduction threshold, and for an analysis of public comments received on the proposed change, and approved those SPAs to the extent that the State was able to resolve any potential access to care issues and determined that access would remain consistent for the Medicaid population. For example, of the 849 SPAs approved in 2019, there were 557 State payment rate changes. Of those, 39 were classified as payment rate reductions or methodology changes that resulted in a reduction in overall provider payment. Within those 39, there were 18 SPAs that sought to reduce payments by less than 4 percent of overall spending within the benefit category, most of which were decreases related to changes in Medicare payment formulas. Sixteen of the remaining 21 SPAs fell into an area discussed in SMDL #17-004 as being unlikely to result in diminished access to covered services, where with the State's analytical support, we were able to determine that the payment rates would continue to comply

²²² See, for example: Indiana Family and Social Services Administration. Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0055/attachment_1.pdf; Colorado Department of Health Care Policy and Financing. Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0087/attachment_1.pdf; The Commonwealth of Massachusetts Executive Office of Health and Human Services Office of Medicaid. Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0020/attachment_1.pdf.

with section 1902(a)(30)(A) of the Act without submitting an AMRP with the SPA. Six of these SPAs represented rate freezes meant to continue forward a prior year's rates or eliminated an inflation adjustment. Six SPAs reduced a payment rate to comply with Federal requirements, such as the Medicaid UPLs in §§ 447.272 and 447.321, the Medicaid DME FFP limit in section 1903(i)(27) of the Act, or the Medicaid hospice rate, per section 1902(a)(13)(B) of the Act. Four SPAs contained reductions that resulted from programmatic changes such as the elimination of a Medicaid benefit or shifting the delivery system for a benefit to coverage by a pre-paid ambulatory health plan. Finally, we found five SPAs for which States were required to submit AMRPs, three of which were submitted to us in 2017 and updated for 2019. Overall, our review of SPAs revealed that smaller reductions may often be a result of elements of the State's approved payment methodology or other requirements that may be outside of the State's control, such as Federal payment limits or changes in the Medicare payment rate formulas that might be incorporated into a State's approved payment methodology, or coding changes that might affect the amount of payment related to the unit of service. We determined, using this information, that it is necessary to provide States with some degree of flexibility in making changes, even if that change is a reduction in provider payment. For example, if a State submits a SPA to reduce or restructure inpatient hospital base or supplemental payments, where inaction on the State's part would result in the State exceeding the applicable UPL, the State would need to reduce inpatient hospital payments or risk a compliance action against the State for violating Medicaid UPL requirements authorized under section 1902(a)(30)(A) of the Act and implementing regulations in 42 CFR 447 subparts C and F. We recognize that this flexibility does not eliminate the need to monitor or consider access to care when making payment rate decisions, but also recognize the need to provide some relief in circumstances where the State must take a rate action to address an issue of compliance with another statutory or regulatory requirement.

Accordingly, we propose that, where a State has provided the information required under proposed paragraphs (c)(1)(i) through (iii), we would consider that the proposed reduction would

result in a nominal payment adjustment unlikely to diminish access below the level consistent with section 1902(a)(30)(A) of the Act and would approve the SPA, provided all other criteria for approval also are met, without requiring the additional analysis that otherwise would be required under proposed § 447.203(c)(2).

Finally, in § 447.203(c)(1)(iii), we propose that the State would be required to provide a supported assurance that the public processes described in § 447.203(c)(4) yielded no significant access to care concerns or yielded concerns that the State can reasonably respond to or mitigate, as appropriate, as documented in the analysis provided by the State under § 447.204(b)(3). The State's response to any access concern identified through the public processes, and any mitigation approach, as appropriate, would be expected to be fully described in the State's submission to us.

We note that the proposed requirement in § 447.203(c)(4) would not duplicate the requirements in current § 447.204(a)(2), as the current § 447.204(a)(2) requires States to consider provider and beneficiary input as part of the information that States are required to consider prior to the submission of any SPA that proposes to reduce or restructure Medicaid service payment rates. The proposed § 447.203(c)(4) describes material that States would be required to include with any SPA submission that proposes to reduce or restructure provider payment rates. As discussed in the CMCS informational bulletin dated June 24, 2016,²²³ before submitting SPAs to us, States are required under § 447.204(a)(2) to make information available so that beneficiaries, providers, and other interested parties may provide input on beneficiary access to the affected services and the impact that the proposed payment change would have, if any, on continued service access. States are expected to obtain input from beneficiaries, providers, and other interested parties, and analyze the input to identify and address access to care concerns. States must obtain this information prior to submitting a SPA to us and maintain

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²²³ CMCS Informational Bulletin, "Federal public notice and public process requirements for changes to Medicaid payment rates." Published June 24, 2016. https://www.medicaid.gov/federal-policy-guidance/downloads/cib062416.pdf. Accessed November 3, 2022.

a record of the public input and how the agency responded to the input. When a State submits the SPA to us, § 447.204(b)(3) requires the State to also submit a specific analysis of the information and concerns expressed in input from affected interested parties. We would rely on this and other documentation submitted by the State, including under proposed § 447.203(c)(1)(iii), (c)(2)(vi), and (c)(4), to inform our SPA approval decisions.

In addition, States are required use the applicable public process required under section 1902(a)(13) of the Act, as applicable, and follow the public notice requirement in § 447.205, as well as any other public processes required by State law (for example, State-specified budgetary process requirements), in setting payment rates and methodologies in view of potential access to care concerns. States have an important role in identifying access to care concerns, including through ongoing and collaborative efforts with beneficiaries, providers, and other interested parties. We understand that not every concern would be easily resolvable, but we anticipate that States would be meaningfully engaged with their beneficiary, provider, and other interested party communities to identify and mitigate issues as they arise. As discussed herein, we would consider information about access concerns raised by beneficiaries, providers, and other interested parties when States propose SPAs to reduce Medicaid payment rates or restructure Medicaid payments and would not approve proposals that do not comport with all applicable requirements, including the access standard in section 1902(a)(30)(A) of the Act.

In feedback received regarding implementation of the AMRP requirements in the 2015 final rule with comment period, States expressed concern about burdensome requirements to draft, seek public input on, and update their AMRP after receiving beneficiary or provider complaints that were later resolved by the State's engagement with beneficiaries and the provider community. Our proposal to require access review procedures specific to State proposals to reduce payment rates or restructure payments would provide an opportunity for the State meaningfully to address and respond to interested parties' input, and seeks to balance State burden concerns with the clear need to understand the perspectives of interested parties most

likely to be affected by a Medicaid payment rate reduction or payment restructuring. Currently, § 447.203(b)(7) requires States to have ongoing mechanisms for beneficiary and provider input on access to care through various mechanisms, and to maintain a record of data on public input and how the State responded to such input, which must be made available to us upon request. We propose to retain this important mechanism and to relocate it to § 447.203(c)(4). Through the cross reference to proposed § 447.203(c)(4) in proposed § 447.203(c)(1)(iii), we would require States to use the ongoing beneficiary and provider feedback mechanisms to aid in identifying and assessing any access to care issues in cooperation with their interested parties' communities, as a component of the streamlined access analysis criteria in proposed § 447.203(c)(1).

Together, we believe the proposed criteria of § 447.203(c)(1)(i) through (iii), where all are met, would establish that a State's proposed Medicaid payment rates and/or payment structure are consistent with the access requirement in section 1902(a)(30)(A) of the Act at the time the State proposes a payment rate reduction or payment restructuring in circumstances when the changes could result in diminished access. Importantly, as noted above, proposed § 447.203(c)(4) (proposed to be relocated from current § 447.203(b)(7)) would ensure that States have ongoing procedures for compliance monitoring independent of any approved Medicaid payment changes.

We previously outlined in SMDL #17-004 several circumstances where Medicaid payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This proposed rule would not codify this list of policies that may produce payment rate

reductions unlikely to diminish access to Medicaid-covered services. However, as a possible addition to the proposed streamlined access analysis criteria in proposed § 447.203(c)(1), we are requesting comment on whether this list of circumstances discussed in SMDL #17-004 should be included in a new paragraph under proposed § 447.203(c)(1) and, if one or more of these circumstances were applicable, the State's proposal would be considered to qualify for the streamlined analysis process under proposed § 447.203(c)(1) notwithstanding the other proposed criteria in proposed paragraph(c)(1).

Proposed paragraph (c)(1) discusses the full set of written assurances and relevant supporting documentation that States would be required to submit with a proposed payment rate reduction or payment restructuring SPA in circumstances when the changes could result in diminished access, where the requirements in proposed paragraphs (c)(1)(i) through (c)(1)(iii) are met. The inclusion of documentation that confirms all criteria proposed in paragraph (c)(1) are met would exempt the State from the requirements in proposed § 447.203(c)(2), discussed later in this section; however, it would not guarantee SPA approval. Proposed payment rate reduction SPAs and payment rate restructuring SPAs meeting the requirements in proposed § 447.203(c)(1) would still be subject to CMS' standard review requirements for all proposed SPAs to ensure compliance with section 1902(a) of the Act, including implementing regulations in part 430. Specifically, and without limitation, this includes compliance with sections 1902(a)(2) of the Act, requiring financial participation by the State in payments authorized under section 1903 of the Act. CMS reviews SPAs involving payments to ensure that the State has identified an adequate source of non-Federal share financing for payments under the SPA so that section 1902(a)(2) of the Act is satisfied; in particular, section 1903(w) of the Act and its implementing regulations establish requirements for certain non-Federal share financing sources that CMS must ensure are met. We further note that a proposed SPA's failure to meet the criteria in proposed paragraph (c)(1) would not result in automatic SPA disapproval; rather, such

proposals would be subject to additional documentation and review requirements, as described in proposed § 447.203(c)(2).

In paragraph (c)(2), we propose the additional, more rigorous State access analysis that States would be required to submit where the State proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) are not met. We believe this more rigorous access analysis should be required because we believe that, where the State is unable to demonstrate that the proposed paragraph (c)(1) criteria are met, more scrutiny is needed to ensure that the proposed payment rates and structure would be sufficient to enlist enough providers so that covered services would be available to beneficiaries at least to the same extent as to the general population in the geographic area. Accordingly, we are proposing in § 447.203(c)(2) to have States document current and recent historical levels of access to care, including a demonstration of counts and trends of actively participating providers, counts and trends of FFS Medicaid beneficiaries who receive the services subject to the proposed payment rate reduction or payment restructuring; and service utilization trends, all for the 3-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA, as a condition for approval. As with the current AMRP process, the information provided by the State would serve as a baseline of understanding current access to care within the State's program, from which the State's payment rate reduction or payment restructuring proposal would be scrutinized.

The 2015 final rule with comment period included requirements that the AMRP process include data on the following topics, in current § 447.203(b)(1)(i) through (v): the extent to which beneficiary needs are fully met; the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service; changes in beneficiary utilization of covered services in each geographic area; the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and

adult populations and for individuals with disabilities); and actual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service. The usefulness of the ongoing AMRP data was directly related to the quality of particular data measures that States selected to use in their AMRPs, and one of the biggest concerns we heard about the process was that States were not always certain that they were providing us with the relevant data that we needed to make informed decisions about Medicaid access to care because the 2015 final rule provided States with a considerable amount of flexibility in determining the type of data that may be provided in support of the State's access analysis included in their AMRP. In addition, States were required to consult with the State's medical advisory committees and publish the draft AMRP for no less than 30 days for public review and comment, per § 447.203(b). Therefore, the final AMRP, so long as the base data elements were met and supported the State's conclusion that access to care in the Medicaid program met the requirements of section 1902(a)(30)(A) of the Act, then the AMRP was accepted by us. As a result, the AMRPs were often very long and complex documents that sometimes included data that was not necessarily useful for understanding the extent of beneficiary access to services in the State or for making administrative decisions about SPAs. In an effort to promote standardization of data measures and limit State submissions to materials likely to assist in ensuring consistency of payment rates with the requirements of section 1902(a)(30)(A) of the Act, we are proposing to maintain a number of the currently required data elements from the AMRP but to be more precise about the type of information that would be required.

In § 447.203(c)(2), we propose that, for any SPA that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access, where the requirements in paragraphs (c)(1)(i) through (iii) are not met, the State would be required to also provide specified information to us as part of the SPA submission as a condition of approval, in addition to the information required under paragraph (c)(1), in a

format prescribed by us. Specifically, in § 447.203(c)(2)(i), we propose to require States to provide a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate FFS Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year. We are proposing to collect this information for SPAs that require a § 447.203(c)(2) analysis, but for those that meet the criteria proposed under § 447.203(c)(1), we are not proposing to require a summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change beyond that which is already provided as part of a normal State plan submission or as may be requested by CMS through the normal State plan review process; we are requesting comment whether these elements should apply to both proposed § 447.203(c)(1) and (c)(2) equally.

In § 447.203(c)(2)(ii), we propose to require the State to provide Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. This proposed element is similar to the current § 447.203(b)(1)(v) rate comparison requirement, which requires the AMRP to include "[a]ctual or estimated levels of provider payment available from other payers, including other public and private payers, by provider type and site of service." However, the proposed analysis specifically would require an aggregate comparison including Medicaid base and supplemental payments, as applicable, before and after the proposed reduction or restructuring are

implemented, compared to the most recently published Medicare payment rates for the same or comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services. We found that, first, States struggled with obtaining and providing private payer data as contemplated by the 2015 final rule with comment period, and, second, States were confused about how to compare Medicaid rates to Medicare rates where there were no comparable services between Medicare and Medicaid. We wanted to acknowledge the feedback we received from States during the AMRP process and modify the requirements in the proposed rule by focusing on the more readily available Medicare payment data as the most relevant payment comparison for Medicaid in this proposed rule, as discussed in detail above. We believe that the E/M CPT/HCPCS code comparison methodology included in the proposed § 447.203(b)(3)(i) and the payment rate disclosure in proposed § 447.203(b)(3)(ii) can serve, at a minimum, as frameworks for States that struggled to compare Medicaid rates to Medicare where there may be no other comparable services between the two programs. Otherwise where comparable services exist, States would be required to compare all applicable Medicaid payment rates within the benefit category to the Medicare rates for the same or comparable services under proposed § 447.203(c)(2)(ii). For reasons mentioned previously in this section, Medicare through MEDPAC engages in substantial analysis of access to care as it reviews payment rates for services, so we believe this is a sufficient benchmark for the Medicaid payment rate analysis.

In § 447.203(c)(2)(iii), we are proposing to require States to provide information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State would be required to provide the number of actively participating providers of services in each affected

benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of actively participating providers in each geographic area over this period. The State could provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area. This data element is similar to current § 447.203(b)(1)(ii), under which States must analyze the availability of care through enrolled providers to beneficiaries in each geographic area, by provider type and site of service, in the AMRP; however, the proposal would require specific quantitative information describing the number of providers, by geographic area, provider type, and site of service available to furnish services to Medicaid beneficiaries and leaves less discretion to the States on specific data measures. With all of the data elements included in proposed paragraph (c)(2), we are proposing that the data come from the 3 years immediately preceding the State plan amendment submission date, as this would provide us with the most recent data and would allow for considerations for data anomalies that might otherwise distort a demonstration of access to care if only 1 year of data was used.

In § 447.203(c)(2)(iv), we are proposing to require States to provide information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish). The State would be required to document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion

of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State would be required to provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. This proposed provision is a combination of current § 447.203(b)(1)(i) and (iv), which require States to provide an analysis of the extent to which beneficiary needs are met, and the characteristics of the beneficiary population (including considerations for care, service and payment variations for pediatric and adult populations and for individuals with disabilities). Even though we are not proposing to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we would require current information on the number of beneficiaries currently receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this beneficiary data is relevant because it provides information about the recipients of Medicaid services and where, geographically, these populations reside to ensure that the statutory access standard is met.

In § 447.203(c)(2)(v), we are proposing to require information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State would be required to provide the number of Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the SPA submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State would be required to document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State would be required to provide quantitative and qualitative information about the Medicaid services furnished in the affected

benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State would be required to provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area. This proposed data element is similar to that currently required in § 447.203(b)(1)(iii), which requires an analysis of changes in beneficiary utilization of covered services in each geographic area. However, as stated earlier, the difference here is that this proposed analysis would be limited to the beneficiary populations impacted by the rate reduction or restructuring, for a more narrow set of data points, rather than requiring the State to conduct a full review of the Medicaid beneficiary population every 3 years on an ongoing basis. Even though we are not proposing to require this analysis to be updated broadly with respect to many benefit categories on an ongoing basis, we would require current information on the number and types of Medicaid services being delivered to Medicaid beneficiaries through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring to inform our SPA review process to ensure that the statutory access standard is met. The inclusion of this data is relevant because it provides information about the actual distribution of care received by Medicaid beneficiaries and where, geographically, these services are provided to ensure that the statutory access standard is met.

Finally, in § 447.203(c)(2)(vi), we are proposing to require a summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2). This proposed requirement mirrors the requirement in § 447.204(b)(3), which requires that for any SPA submission that proposes to reduce or restructure Medicaid service payment rates, a specific analysis of the information and concerns expressed in input from affected interested parties must be provided at the time of the

SPA submission. The new proposed § 447.203(c)(2)(vi) requires the same analysis while providing more detail as to what we expect the State to provide. Specifically, proposed § 447.203(c)(2)(vi) would require information about concerns and complaints from beneficiaries and providers specifically, as well as from other interested parties, and would underscore that the required analysis would be required to include the State's responses.

Where any of the previously discussed proposed data elements requires an analysis of data over a 3-year period, we are proposing this time span to smooth statistical anomalies, and so that data variations can be understood. For example, any 3-year period look-back that includes portions of time during a public health emergency, such as that for the COVID-19 pandemic, might include much more variation in the access to care measures than periods before or after the public health emergency. By using a 3-year period, it is more likely that the State, CMS, and other interested parties would be able to identify and appropriately account for short term disruptions in access-related measures, for example, when the number of services performed dropped precipitously in 2020 as elective visits and procedures were postponed or canceled due to the public health emergency.²²⁴ If the proposed rule only included a 12-month period, for example, it might not be clear that the data represent an accurate reflection of access to care at the time of the proposed reduction or restructuring. For example, a State may see variation in service utilization if there have been programmatic changes that are introduced over time, such as a move to increase care provided through a managed care delivery system in the State through which the fee-for-service utilization declines steadily until managed care enrollment targets are achieved, but a one-time review of that fee-for-service utilization capturing just a 12-month period might not capture data most reflective of the current fee-for-service utilization demonstrating access to care consistent with section 1902(a)(30)(A) of the Act. We are seeking public comment on the proposed use of a 3-year period where the proposed rule would require

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²²⁴ Stuart, B. "How The COVID-19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead." *Health Affairs*, October 8, 2020. Available at https://www.healthaffairs.org/do/10.1377/forefront.20201006.263687 (accessed February 27, 2023).

data about trends over time in the data elements proposed to be required under § 447.203(c)(2). We are also seeking public comment on the data elements required in § 447.203(c)(2) as additional State rate analysis.

Proposed paragraph (c)(2) would require that States conduct and provide to us a rigorous analysis of a proposed payment rate reduction's or payment restructuring's potential to affect beneficiary access to care. However, by limiting these analyses to only those proposed payment rate reductions and payment restructurings in circumstances when the changes could result in diminished access that do not meet the criteria in proposed paragraph (c)(1), we believe that the requirements proposed in paragraph (c)(2) would help to enable us to determine whether the proposed State Medicaid payment rates and payment methodologies are consistent with section 1902(a)(30)(A) of the Act while minimizing State and Federal administrative burden, to the extent possible. We would use this State-provided information and analysis to help us understand the current levels of access to care in the State's program, and determine, considering the provider, beneficiary, and other interested party input collected through proposed § 447.203(c)(4), whether the proposed payment rate reduction or payment restructuring likely would reduce access to care for the particular service(s) consistent with the statutory standard in section 1902(a)(30)(A) of the Act. If we approve the State's proposal, the data provided would serve as a baseline for prospective monitoring of access to care within the State.

The proposed analysis and documentation requirements in paragraph (c)(2) draw, in part, from the current requirements of the AMRP process in the current § 447.203(b)(1), and reflect the diverse methods and measures that are and can be used to monitor access to care. We also drew on some of the comments received on the 2011 proposed rule, as discussed in the 2015 final rule with comment period, where several commenters recommended that CMS consider identifying a set of uniform measures that States must collect data on or that CMS weighs more heavily in its analysis.²²⁵ We are proposing to provide more specificity on the types of uniform

²²⁵ 80 FR 67576 at 67590

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data elements in this proposed rule in § 447.203(c) than is provided under current § 447.203(b)(1). States have shown that they have access to the data listed in the proposed § 447.203(c)(2) when we have requested it during SPA reviews and through the AMRP process, and through this proposed rule, we are proposing to specify the type of data that we would expect States to provide with rate reduction or restructuring SPAs that do not meet the proposed criteria for streamlined analysis under § 447.203(c)(1). As noted elsewhere in the preamble, the ongoing AMRP requirements have presented an administratively burdensome process for States to follow every 3 years, particularly where we did not provide States with the specific direction on the types of data elements we preferred for States to include. However, the data elements involved in the current AMRP process in § 447.203(b)(1) can provide useful information about beneficiary access to care in current § 447.203(b)(1)(i), (iii), and (iv); Medicaid provider availability in current § 447.203(b)(1)(ii); and about payment rates available from other payers, which may affect Medicaid beneficiaries' relative ability to access care, in current § 447.203(b)(1)(v). We found that the AMRPs were most relevant when updated to accompany a submission of rate reduction or restructuring SPAs as specified in the current § 447.203(b)(6); accordingly, to better balance ongoing State and Federal administrative burden with our need to obtain access-related information to inform our approval decisions for payment rate reduction or restructuring SPAs, we are proposing to end the ongoing AMRP requirement but maintain a requirement that States include similar data elements when submitting such SPAs to us that do not qualify for the proposed streamlined analysis process under § 447.203(c)(1).

The proposed analyses in paragraph (c)(2) would enable us to focus our review of Medicaid access to care on proposals that may result in diminished access to care, enabling us to more substantively review a proposed rate reduction's or restructuring's potential impact on access (for example, counts of participating providers), realized access (for example, service utilization trends), and the beneficiary experience of care (for example, characteristics of the beneficiary population, beneficiary utilization data, and information related to feedback from

beneficiaries and other interested parties collected during the public process and through ongoing beneficiary feedback mechanisms, along with the State's responses to that feedback), while also being able to more quickly work through a review of nominal rate reduction SPAs for which States have demonstrated certain levels of payment and for which the public process did not generate access to care concerns. By including information on provider type and site of service, we believe States would be able to demonstrate access to the services provided under a specific benefit category within a number different settings across the Medicaid program, such as the availability of physicians services delivered in a physician practice, clinic setting, FQHC or RHC, or even in a hospital-based office setting. We believe that by defining specific data elements which must be provided to support a payment rate reduction SPA would create a more predictable process for States and for CMS in conducting the SPA review than under the current AMRP process in § 447.203(b)(6).

Furthermore, data elements proposed to be required under proposed § 447.203(c)(2) would be based on State-specified geographic stratifications, to help ensure we can perform access review consistent with the requirements of section 1902(a)(30)(A) of the Act. We expect that States would have readily available access to geographically differential beneficiary and provider data. Some of this information is available through CMS-maintained resources, such as the Transformed Medicaid Statistical Information System (T-MSIS), and other data is available through the National Plan and Provider Enumeration System (NPPES), but we believe that States should have their own data systems that would allow them to generate the most up-to-date beneficiary utilization and provider enrollment data, stratified by geographic areas within the State. States should use the most recent complete data available for each of the proposed data elements, and each would be required to be demonstrated to CMS by State-specified geographic area. We believe that the geographic stratification would enable CMS to establish a baseline for Medicaid access to care within the geographic areas so that we can determine if current levels of access to care are consistent with section 1902(a)(30)(A) of the Act, and can make future

determinations if access is diminished in the future within the geographic area. For all of the data elements in proposed § 447.203(c)(2), the more geographic differentiation that can be provided (that is, the smaller and more numerous the distinct geographic areas of the State that are selected for separate analysis), the more we believe that the State can meaningfully demonstrate that the proposed rate changes are consistent with the access standard in section 1902(a)(30)(A) of the Act, which requires that States assure that payments are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

If finalized, we anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the *Comparative Payment Rate Analysis Timeframe* proposed in § 447.203(b)(4). In the intervening period, we anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

In § 447.203(c)(3), we propose mechanisms for ensuring compliance with requirements for State analysis for rate reduction or restructuring, as specified in proposed paragraphs (c)(1) and (c)(2), as applicable. We propose that a State that submits a SPA that proposes to reduce provider payments or restructure provider payments that fails to provide the required information and analysis to support approval as specified in proposed paragraphs (c)(1) and (2), as applicable, may be subject to SPA disapproval under § 430.15(c). Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed SPA, including any raised by CMS in our review of the proposal and any raised through the public process as specified in proposed paragraph (c)(4) of this section, or under § 447.204(a)(2), may be subject to SPA disapproval under § 430.15(c). Disapproving a SPA means that the State would not have authority to implement the proposed rate reduction or restructuring and would be required to continue to pay providers according to the rate methodology described in the approved State plan. Proposed paragraph (c)(3) would further

provide that if, after approval of a proposed rate reduction or restructuring, State monitoring of beneficiary access shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in the number of beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, we may take a compliance action. As described in § 447.204(d), compliance actions would be carried out using the procedures described in § 430.35.

As discussed in the prior section, we are proposing to move current § 447.203(b)(7) to proposed § 447.203(c)(4). We are not proposing any changes to the public process described in current paragraph (b)(7). If the other provisions of this proposed rule are finalized, we would redesignate paragraph (b)(7) as paragraph (c)(4). The ability for providers and beneficiaries to provide ongoing feedback to the State regarding access to care and a beneficiary's ability to access Medicaid services is essential to the Medicaid program in that it provides the primary interested parties the opportunity to communicate with the State and for the State to track and take account of those interactions in a meaningful way. The ongoing mechanisms for provider and beneficiary feedback must be retained in this proposed rule as this process serves an important role in determining whether or not the public has raised concerns regarding access to Medicaid-covered services, which would inform the State's approach to ongoing Medicaid provider payment rates and methodologies, and whether related proposals would be approvable.

We are proposing to move current § 447.203(b)(8) to proposed § 447.203(c)(5) to better organize § 447.203 to reflect the policies in this proposed rule. We are not proposing any changes to the methods for addressing access questions and remediation of inadequate access to care, as described in current paragraph (b)(8). If the other provisions of this proposed rule are finalized, we would redesignate paragraph (b)(8) as paragraph (c)(5). It is important to retain this provision because we acknowledge that there may be access issues that come about apart

from a specific State payment rate action, and there must be mechanisms through which those issues can be identified and corrective action taken.

Finally, we are proposing to move current § 447.204(d) to proposed § 447.203(c)(6). We believe the subject matter, of compliance actions for an access deficiency, is better aligned to the proposed changes in § 447.203. We are not proposing any changes to defining the remedy for the identification of an unresolved access deficiency, as described in current § 447.204(d). If the other provisions of this proposed rule are finalized, we would redesignate § 447.204(d) as paragraph (c)(6).

We are seeking public comment on our proposed procedures and requirements for State analysis for payment rate reduction or payment restructuring SPAs, including the qualification criteria for streamlined analysis proposed in § 447.203(c)(1), the proposed additional analysis elements in § 447.203(c)(2) for those proposed payment rate reductions or payment restructurings that do not meet the criteria in paragraph (c)(1), the proposed methods for ensuring compliance in § 447.203(c)(3), the proposed mechanisms for ongoing beneficiary and provider input in § 447.203(c)(4), the proposed methods to address access questions and remediation of inadequate access to care in § 447.203(c)(5), and the proposed compliance actions for access deficiencies in § 447.203(c)(6).

4. Medicaid provider participation and public process to inform access to care (§ 447.204)

In § 447.204, we propose conforming changes to reflect proposed changes in § 447.203, if finalized. These conforming edits are limited to § 447.204(a)(1) and (b) and are necessary for consistency with the newly proposed changes in § 447.203(b). The remaining paragraphs of § 447.204 would be unchanged.

Specifically, we propose to update the language of § 447.204(a)(1), which currently references § 447.203, to reference § 447.203(c). Because we are proposing wholesale revisions to § 447.203(b) and the addition of § 447.203(c), the proposed data and analysis referenced in the current citation to § 447.203 would be located more precisely in § 447.203(c). Current

§ 447.204(b)(1) refers to the State's most recent AMRP performed under current § 447.203(b)(6) for the services at issue in the State's payment rate reduction or payment restricting SPA; we propose to remove this requirement to align with our proposal to rescind the AMRP requirements in current § 447.203(b). Current § 447.204(b)(2) and (3) require the State to submit with such a payment SPA an analysis of the effect of the change in the payment rates on access and a specific analysis of the information and concerns expressed in input from affected interested parties; we believe these current requirements are addressed in proposed § 447.203(c)(1) and (2), as applicable. We believe that the continued inclusion of these paragraphs (b)(2) and (3) would be unnecessary or redundant in light of the proposals in § 447.203(c)(1) and (2), if finalized. The objective processes proposed under § 447.203(c)(1) and (2), which would require States to submit quantitative and qualitative information with a proposed payment rate reduction or payment restructuring SPA, would be sufficient for us to obtain the information necessary to assess the State's proposal with the same or similar information as currently is required under § 447.204(b)(2) and (3).

With the removal of § 447.204(b)(1) through (b)(3), we propose to revise § 447.204(b) to read, "[t]he State must submit to us with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter."

Finally, as noted in the previous section, we propose to remove and relocate § 447.204(d), as we felt the nature of that provision is better suited to codification in § 447.203(c)(6).

We are seeking public comment on the proposed amendments to § 447.204.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget

(OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our Agency.
 - The accuracy of our estimate of the information collection Burden.
 - The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (see section III.E. of this preamble for further information). Comments, if received, will be responded to within the subsequent final rule.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2021 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs²²⁶ (calculated at 100 percent of salary), and our adjusted hourly wage.

 $^{{\}it 226 https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.}$

TABLE 1: National Occupational Employment and Wage Estimates

Occupation Title	Occupational Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs(\$/hr)	Adjusted Hourly Wage (\$/hr)
Administrative Services Manager	11-3012	54.34	54.34	108.68
Business Operations Specialist	13-1000	38.64	38.64	77.28
Business Operations Specialist, All Other	13-1199	38.10	38.10	76.20
Chief Executive	11-1011	102.41	102.41	204.82
Compensation, Benefits, and Job	13-1141	35.49	35.49	70.98
Analyst				
Computer and Information Analyst	15-1210	50.40	50.40	100.80
Computer Programmer	15-1251	46.46	46.46	92.92
Data Entry Keyers	43-9021	17.28	17.28	34.56
General and Operations Manager	11-1021	55.41	55.41	110.82
Human Resources Manager	11-3121	65.67	65.67	131.34
Management Analyst	13-1111	48.33	48.33	96.66
Social and Community Service	11-9151	36.92	36.92	73.84
Managers				
Social Science Research Assistants	19-4061	27.13	27.13	54.26
Statistician	15-2041	47.81	47.81	95.62
Survey Researcher	19-3022	31.10	31.10	62.20
Training and Development Specialist	13-1151	32.51	32.51	65.02

For States and the private sector the employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that there is no practical alternative and that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We believe that the costs for beneficiaries undertaking administrative and other tasks on their own time is a post-tax hourly wage rate of \$20.71/hr.

We adopt an hourly value of time based on after-tax wages to quantify the opportunity cost of changes in time use for unpaid activities. This approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." [*] We start with a measurement of the usual weekly earnings of wage and salary

workers of \$998. [**] We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of \$24.95. We adjust this hourly rate downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in a post-tax hourly wage rate of \$20.71. We adopt this as our estimate of the hourly value of time for changes in time use for unpaid activities .²²⁷ ²²⁸ Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Adjustment to State Cost Estimates

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. The Federal government provides funding based on an FMAP that is established for each State, based on the per capita income in the State as compared to the national average. FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capital incomes. For Medicaid, all States receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. As such, and taking into account the Federal contribution to the costs of administering the Medicaid programs for purposes of estimate State burden with respect to collection of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs, even though the burden would likely be much smaller.

- C. Proposed Information Collection Requirements (ICRs)
- 1. ICRs Regarding Medicaid Advisory Committee and Beneficiary Advisory Group (§ 431.12)

²²⁷ Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation. 2017. "Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices." https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.

²²⁸ U.S. Bureau of Labor Statistics. Employed full time: Median usual weekly nominal earnings (second quartile): Wage and salary workers: 16 years and over [LEU0252881500A], retrieved from FRED, Federal Reserve Bank of St. Louis; https://fred.stlouisfed.org/series/LEU0252881500A. Annual Estimate, 2021.

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10845). At this time, the control number is to be determined (TBD). OMB will assign the control number upon their clearance of this new collection of information request. The control number will be set out in the subsequent final rule (CMS-2442-F).

Currently, most States have an established Medicaid Advisory Committee (MAC, previously known as a Medical Care Advisory Committee, or MCAC) whereby each State has the discretion on how to operate its MAC. A small number of States also use consumer advisory subcommittees as part of their MACs, similar to the Beneficiary Advisory Groups (BAGs) in proposed § 431.12. We reviewed data from 10 States to determine the current status of MACs and to determine the burden needed to comply with the proposed § 431.12 requirements across 50 States and the District of Columbia.

Under the proposed provision, States would be required to:

- Appoint members to the MAC and BAG on a rotating and continuous basis.
- Develop and publish a process for MAC and BAG member recruitment and appointment and selection of MAC and BAG leadership.
 - Develop and publish:
 - ++ Bylaws for governance of the MAC.
 - ++ A current list of MAC and BAG membership.
 - ++ Past meeting minutes, including a summary from the most recent BAG Meeting.
 - Develop, publish, and implement a regular meeting schedule for the MAC and BAG.

Additionally, the State must provide and post to its website an annual report written by the MAC to the State describing its activities, topics discussed, recommendations. The report must also include actions taken by the State based on the MAC recommendations.

The proposed requirements would require varying levels of effort by States. For example, a handful of States already have a BAG. However, we believe that most States will be required to create new structures and processes. The majority of States reviewed are already

meeting some of the new proposed requirements for MACs, such as publication of meeting schedules, publication of membership lists, and publication of bylaws. However, all MAC bylaws would need to be updated to meet the new proposed requirements. Our review showed that most States are not currently publishing their recruitment and appointment processes for MAC members, and those that did would need to update these processes to meet the new proposed requirements. About half of the States reviewed published meeting minutes with responses and State actions, as required under the new proposed requirements. But only one State reviewed published an annual report, so this will likely be a new requirement for almost all State MACs. States will not need to modify or build a reporting systems to create and post these annual reports. Due to the wide range in the use and maturity of current MCACs across the States, we are providing a range of estimates to address these variations. We recognize that some States, which do not currently operate a MCAC, will have a higher burden to implement the requirements of § 431.12 to shift to the MAC and BAG structure. However, our research showed that the majority of States do have processes and procedures for their current MCACs, which will require updating, but at a much lower burden. Therefore, we believe it is appropriate to offer average low and high burden estimates.

For a low estimate, we estimate it would take a team of business operations specialists 120 hours at \$76.20/hr to develop and publish the processes and report. In aggregate, we estimate an annual burden of 6,120 hours (120 hr/response x 51 responses) at a cost of \$466,344 (6,120 hr x \$76.20/hr). We also estimate that it would take 40 hours at \$131.34/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAG leadership which would occur every 2 years. In aggregate, we estimate a biennial burden of 2,040 hours (40 hr/response x 51 responses) at a cost of \$267,934 (2,040 hr x \$131.34/hr). Additionally, we estimate it would take 10 hours at \$110.82/hr for an operations manager to review the updates and prepare the required reports for annual publication. In aggregate, we estimate an annual burden of 510 hours (10 hr/response x 51 responses) at a

cost of \$56,518 (510 hr x \$110.82/hr).

We derived the high estimate by doubling the hours from the low estimate. We used this approach because all States already have a MCAC requirement which means the type of work being discussed is already underway in most States and that there is reference point for the type of work described. For example, we estimate it would take a team of business operations specialists 240 hours at \$76.20/hr to develop and publish the processes and annual report. In aggregate, we estimate an annual burden of 12,240 hours (240 hr/response x 51 responses) at a cost of \$932,688 (12,240 hr x \$76.20/hr). We also estimate that it would take 80 hours at \$131.34/hr for a human resources manager to review and approve bylaws and help with recruitment and appointment and selection of MAC and BAG leadership which would occur every 2 years. In aggregate, we estimate a biennial burden of 4,080 hours (80 hr/response x 51 responses) at a cost of \$535,867 (4,080 hr x \$131.34). Additionally, we estimate it would take 20 hours at \$110.82/hr for an operations manager to review the updates and prepare the required annual report for publication. In aggregate, we estimate an annual burden of 1,020 hours (20 hr/response x 51 responses) at a cost of \$113,036 (1,020 hr x \$110.82/hr).

We have summarized the total burden in Table 2. To be conservative and not underestimate our burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

TABLE 2: Summary of Burden Estimates for Medical Care Advisory Committee Requirements

Requirem ent	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 431.12 (develop/ publish report)	51	51	Annual	240	12,240	76.20	932,688	466,344
§ 431.12 (review/ap prove bylaws)	51	51	Biennial	80	4,080	131.34	535,867	267,934
§ 431.12 (review updates/pr epare reports)	51	51	Annual	20	1,020	110.82	113,036	56,518
Total	51	153	varies	Varies	17,340	varies	1,581,591	790,795

2. ICRs Regarding Person-Centered Service Plans (§ 441.301(c)(3); cross-referenced to §§ 441.450(c), 441.540(c), and 441.725(c), and part 438)

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

Section 1915(c)(1) of the Act requires that services provided through section 1915(c) waiver programs be provided under a written plan of care (hereinafter referred to as "personcentered service plans" or "service plans"). Existing Federal regulations at § 441.301(c) address

the person-centered planning process and include a requirement at § 441.301(c)(3) that the person-centered service plan be reviewed and revised upon reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly or at the request of the individual.

In 2014, we released guidance for section 1915(c) waiver programs²²⁹ (hereinafter the "2014 guidance") that included expectations for State reporting of State-developed performance measures to demonstrate compliance with section 1915(c) of the Act and the implementing regulations in part 441, subpart G through six assurances, including assurances related to person-centered service plans. The 2014 guidance also indicated that States should conduct systemic remediation and implement a Quality Improvement Project when they score below an 86 percent threshold on any of their performance measures. Based on feedback CMS obtained during various public engagement activities conducted with States and other interested parties over the past several years about the reporting discussed in the 2014 guidance, as well as feedback received through the RFI²³⁰ discussed earlier about the need to standardize reporting and set minimum standards for HCBS, we are proposing a different approach for States to demonstrate that they meet the statutory requirements in section 1915(c) of the Act and the regulatory requirements in part 441, subpart G, including the requirements regarding assurances around service plans.

Within this rule we propose to replace expectations for State reporting of State-developed performance measures and the 86 percent performance threshold included in the 2014 guidance and codify requirements for reporting on standardized measures and a minimum performance level for States to demonstrate that they meet the existing person-centered service plan requirements at § 441.301(c)(3). Specifically, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least

²²⁹ Modifications to Quality Measures and Reporting in § 1915(c) Home and Community-Based Waivers. March 2014. Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_2.pdf. CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. At § 441.311(b)(3), we propose to modernize the service plan reporting requirement by standardizing State reporting through new Federal reporting requirements. These performance and reporting requirements, in combination with other proposed requirements²³¹ identified throughout this proposed rule, are intended to supersede and fully replace existing reporting requirements and required performance levels for section 1915(c) waiver programs, which were established through the 2014 guidance discussed earlier.²³² We propose to apply these requirements to services delivered under FFS or managed care delivery systems. Further, we propose to apply the proposed requirements at § 441.301(c)(3) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.450(c), 441.540(c), and 441.725(c), respectively. In addition, we propose to reposition, specify, and remove extraneous language from § 441.301(c)(1).

a. One Time Person-Centered Service Plan Requirements: State (§ 441.301(c)(3))

As discussed above, at new § 441.301(c)(3)(ii)(A), we propose to require that States demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. We also propose, at new § 441.301(c)(3)(ii)(B), to require that States demonstrate that they reviewed the person-centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. The burden associated with

²³¹ The other requirements relate to incident management, critical incident, person centered planning, and service provision compliance reporting; reporting on the HCBS Quality Measure Set; access reporting; and payment adequacy reporting.

²³² Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Waivers. March 2014 Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative 0 71.pdf.

the person-centered service plan reporting requirements proposed at § 441.301(c)(3)(ii)(A) and (B) will affect the 48 States (including the District of Columbia) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.²³³ We anticipate that States will need to update State policy and oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with requirements.

However, because we are codifying a minimum performance level associated with existing regulations but not otherwise changing the regulatory requirements under § 441.301(c)(3)(ii)(A) and (B), we do not estimate any additional burden related to those requirements. We also hold that there is no additional burden associated with repositioning, specifying, and removing extraneous language from the regulatory text at § 441.301(c)(1). In this regard we are only estimating burden for updating State policy and oversight and monitoring processes related to the codification of the new 90 percent minimum performance level associated with requirements.

We estimate it would take 8 hours at \$108.68/hr for an administrative services manager to update State policy and oversight and monitoring processes, 2 hours at \$110.82/hr for a general and operations manager to review and approve the updates to State policy and oversight and monitoring processes, and 1 hour at \$204.82/hr for a chief executive to review and approve the updates to State policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 528 hours (48 States x [8 hr + 2 hr + 1 hr]) at a cost of \$62,203 (48 States x [(8 hr x \$108.68/hr) + (2 hr x \$110.82/hr) + (1 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$31,102 (\$62,203 x 0.50).

²³³ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

TABLE 3: Summary of One-Time Burden Estimates for States for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Update State policy and oversight and monitoring processes	48	48	Once	8	384	108.68	41,733	20,867
Review and approval of State policy update at the management level	48	48	Once	2	96	110.82	10,639	5,319
Review and approval of State policy update at the chief executive level	48	48	Once	1	48	204.82	9,831	4,916
Total	48	144	Once	11	528	Varies	62,203	31,102

b. One Time Person-Centered Service Plan Requirements: Managed Care Entities (§ 441.301(c)(3))

As discussed earlier in sections II.B.1 of this preamble, we are proposing to also apply, to managed care delivery systems, the requirements at § 441.301(c)(3) to demonstrate that a reassessment of functional need was conducted at least annually for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days and to demonstrate that they reviewed the person centered service plan and revised the plan as appropriate based on the results of the required reassessment of functional need at least every 12 months for at least 90 percent of individuals continuously enrolled in the waiver for at least 365 days. As with the burden estimate for States, we do not estimate an ongoing burden related to the codification of a minimum performance level associated with the requirements at § 441.301(c)(3).

For managed care entities we estimate it would take 5 hours at \$108.68/hr for an administrative services manager to update organizational policy and oversight and monitoring processes related to the codification of a new minimum performance level and 1 hour at

\$204.82/hr for a chief executive to review and approve the updates to organizational policy and oversight and monitoring processes. In aggregate, we estimate a one-time burden of 966 hours (161 managed care entities x [5 hr + 1 hr]) at a cost of \$120,463 (161 managed care entities x [(5 hr x \$108.68/hr) + (1 hr x \$204.82/hr)]).

TABLE 4: Summary of One-Time Burden Estimates for Managed Care Entities (MCEs) for the Person-Centered Service Plan Requirements at § 441.301(c)(3)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Update organizational policy and oversight and monitoring processes	161	161	Once	5	805	108.68	87,487	n/a
Review and approval of policy and oversight and monitoring processes	161	161	Once	1	161	204.82	32,976	n/a
Total	161	322	Once	6	966	Varies	120,463	n/a

3. ICRs Regarding Grievance System (§ 441.301(c)(7); cross-referenced to §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), and part 438)

At § 441.301(c)(7), we propose to require that States establish grievance procedures for Medicaid beneficiaries receiving section 1915(c) waiver program services through a FFS delivery system to file a complaint or expression or dissatisfaction related to the State's or a provider's compliance with the person-centered planning and service plan requirements at § 441.301(c)(1) through (3) and the HCBS settings requirements at § 441.301(c)(4) through (6).

Proposed § 441.301(c)(7)(vii) lists proposed recordkeeping requirements related to grievances. Specifically, at § 441.301(c)(7)(vii)(A), we propose to require that States maintain records of grievances and review the information as part of their ongoing monitoring procedures. At § 441.301(c)(7)(vii)(B)(1) through (7), we propose to require that the record of each grievance must contain the following information at a minimum: a general description of the reason for the grievance, the date received, the date of each review or review meeting (if

applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed. Further, at § 441.301(c)(7)(vii)(C), we propose to require that grievance records be accurately maintained and in a manner that would be available upon our request.

We also propose to apply these proposed requirements in § 441.301(c)(7) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii), respectively. However, to avoid duplication with the grievance requirements at part 438, subpart F, we do not propose to apply these requirements to managed care delivery systems.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our reporting tools and survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the grievance system requirements proposed at § 441.301(c)(7) will affect the 48 States (including the District of Columbia) that deliver at least some HCBS under sections 1915(c), (i), (j), or (k) authorities through FFS delivery

systems.^{234,235} While some States may have existing grievance systems in place for their FFS delivery systems, we are unable to determine the number of States with existing grievance systems or whether those grievance systems would meet the proposed requirements at § 441.301(c)(7). As a result, we do not take this information into account in our burden estimate. We estimate a one-time and on-going burden to implement these requirements at the State level.

Specifically, States will have to: (1) develop and implement policies and procedures; (2) establish processes and data collection tools for accepting, tracking, and resolving, within required timeframes, beneficiary grievances, including processes and tools for: providing beneficiaries with reasonable assistance with filing a grievance, for accepting grievances orally and in writing, for reviewing grievance resolutions with which beneficiaries are dissatisfied, and for providing beneficiaries with a reasonable opportunity to present evidence and testimony and make legal and factual arguments related to their grievance; (3) inform beneficiaries, providers, and subcontractors about the grievance system; and (4) develop beneficiary notices; and collect and maintain information on each grievance, including the reason for the grievance, the date received, the date of each review or review meeting (if applicable), resolution and date of the resolution of the grievance (if applicable), and the name of the beneficiary for whom the grievance was filed.

i. One-Time Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the one-time requirements, we estimate it would take: 240 hours at \$108.68/hr for an administrative services manager to draft policy and procedure content, prepare notices and informational materials, draft rules for publication, and conduct public hearings; 100 hours at \$92.92/hr for a computer programmer to build, design, and operationalize internal

²³⁴ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

²³⁵ While some States deliver the vast majority of HCBS through managed care delivery systems, States would be subject to these requirements if they deliver any HCBS under section 1915(c), (i), (j), or (k) authorities through a fee-for service delivery system. Based on data showing that the percent of LTSS expenditures delivered through managed LTSS delivery systems varied between 3 percent and 93 percent in 2019 across all States with managed LTSS, we assume that all States deliver at least some HCBS through fee-for-service delivery systems (https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltssexpenditures2019.pdf). We anticipate that the burden associated with implementing these requirements will be lower for States that deliver the vast majority of HCBS through managed care delivery systems.

systems for data collection and tracking; 120 hours at \$65.02/hr for a training and development specialist to develop and conduct training for staff; 40 hours at \$110.82/hr for a general and operations manager to review and approve policies, procedures, rules for publication, notices, and training materials; and 20 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate a one-time burden of 24,960 hours (520 hr x 48 States) at a cost of \$2,481,926 (48 States x [(240 hr x \$108.68/hr) + (100 hr x \$92.92/hr) + (120 hr x \$65.02/hr) + (40 hr x \$110.82/hr) + (20 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$1,240,963 (\$2,481,926 x 0.50).

TABLE 5: Summary of One-Time Burden Estimates for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft policy and procedures, rules for publication; prepare beneficiary notices, informational materials; conduct public hearings	48	48	Once	240	11,520	108.68	\$1,251,994	625,997
Build, design, operationalize internal systems for data collection and tracking	48	48	Once	100	4,800	92.92	\$446,016	223,008
Develop and conduct training for staff	48	48	Once	120	5,760	65.02	\$374,515	187,258
Review and approve policies, procedures, rules for publication, notices, and training materials at the management level	48	48	Once	40	1,920	110.82	\$212,774	106,387
Review and approve all operations in collection of information requirement at the chief executive level	48	48	Once	20	960	204.82	\$196,627	98,314
TOTAL	48	240	Once	520	24,960	Varies	\$2,481,926	1,240,964

ii. Ongoing Grievance System Requirements: States (§ 441.301(c)(7))

With regard to the on-going requirements, we estimate that approximately 2 percent of 1,460,363 Medicaid beneficiaries who receive HCBS under section 1915(c), (i), (j), or (k) authorities through FFS delivery systems annually²³⁶ will file a grievance or appeal (29,207 grievances = 1,460,363 x 0.02)²³⁷. We estimate it would take: 0.333 hours or 20 minutes at \$76.20/hr for a business operations specialist to collect the required information for each

²³⁶ https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.

²³⁷ We based this percent on an estimate of the percent of Medicaid beneficiaries that file appeals and grievances in Medicaid managed care in Supporting Statement A for the information collection requirements for the Medicaid managed care file rule (CMS-2408-F, RIN 0938-AT40). See https://omb.report/icr/202205-0938-015/doc/121334100 for more information.

grievance from the beneficiary, 0.166 hours or 10 minutes at \$34.56/hr for a data entry worker to record the required information on each grievance, 20 hours at \$92.92/hr for a computer programmer to maintain the system for storing information on grievances, 12 hours at \$110.82/hr for a general and operations manager to monitor and oversee the collection and maintenance of the required information, and 2 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement. In aggregate, we estimate an on-going burden of 16,206 hours at a cost of \$1,081,374 ([(29,207 grievances x 0.333 hr x \$76.20/hr) + (29,207 grievances x 0.166 hr x \$34.56/hr) + (48 States x 20 hr x \$92.92/hr) + (48 States x 12 hr x \$110.82/hr) + (48 States x 2 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$540,687 (\$1,081,374 x 0.50) per year.

TABLE 6: Summary of Ongoing Burden for States for the Grievance System Requirements at § 441.301(c)(7)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect required grievance data and information	48	29,207	On occasion	0.333	9,726	76.20	741,116	370,558
Enter required grievance data and information into data collection and tracking system	48	29,207	On occasion	0.166	4,848	34.56	167,559	83,780
Perform maintenance on system for storing data and information on grievances	48	48	Annually	20	960	92.92	89,203	44,602
Monitor and oversee the collection and maintenance of the required information at the management level	48	48	Annually	12	576	110.82	63,832	31,916
Review and approve all operations associated with collection of information requirement at the executive level	48	48	Annually	2	96	204.82	19,663	9,831
TOTAL	48	58,558	Varies	Varies	16,206	Varies	1,081,374	540,687

4. ICRs Regarding Incident Management System (§ 441.302(a)(6); cross-referenced to §§ 441.464(e), 441.570(e), 441.745(a)(1)(v), and part 438)

At § 441.302(a)(6), we propose to require that States provide an assurance that they operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. At § 441.302(a)(6)(i)(A), we propose to establish a minimum standard definition of a critical incident. At § 441.302(a)(6)(i)(B), we propose to require that States have electronic incident management systems that, at a minimum,

enable electronic collection, tracking (including of the status and resolution of investigations), and trending of data on critical incidents. At § 441.302(a)(6)(i)(C), we propose to require States to require providers to report to States any critical incidents that occur during the delivery of section 1915(c) waiver program services as specified in a waiver participant's person-centered service plan, or are a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(D), we propose to require that States use claims data, Medicaid Fraud Control Unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of section 1915(c) waiver program services, or as a result of the failure to deliver authorized services. At § 441.302(a)(6)(i)(E), we propose to require that States share information on the status and resolution of investigations if the State refers critical incidents to other entities for investigation. We also propose, at § 441.302(a)(6)(i)(F), to require States to separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes. At § 441.302(a)(6)(i)(G), we propose to require that States meet the reporting requirements at § 441.311(b)(1) related to the performance of their incident management systems. We also propose to codify minimum performance levels to demonstrate that States meet the requirements at § 441.302(a)(6). These performance and reporting requirements, in combination with other proposed requirements identified throughout this proposed rule, are intended to supersede and fully replace existing reporting requirements and required performance levels for section 1915(c) waiver programs, which were established in $2014.^{238}$

At § 441.302(a)(6)(iii), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. We also propose to apply the proposed

²³⁸ Modifications to Quality Measures and Reporting in §1915(c) Home and Community-Based Waivers. March 2014 Accessed at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative 0 71.pdf.

requirements § 441.302(a)(6) to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.570(e), 441.464(e), and 441.745(a)(1)(v), respectively.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the incident management system requirements proposed at § 441.302(a)(6) will affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), (i), (j), or (k) authorities.²³⁹ We estimate a one-time and on-going burden to implement these requirements at the State level. The burden for the proposed reporting requirements at § 441.311(b)(1) is included in the ICR #8, which is the ICRs Regarding Compliance Reporting (§ 441.311(b)).

All of the States impacted by § 441.302(a)(6)(i)(B), requiring that States use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, have existing incident management systems in place. However, we assume that all States will need to make at least some changes to their existing systems to fully comply with the proposed requirements. Specifically, States will have to update State policies and procedures; implement

²³⁹ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

new or update existing electronic incident management systems; publish revised provider requirements through State notice and publication processes; update provider manuals and other policy guidance; amend managed care contracts; collect required information from providers; use other required data sources to identify unreported incidents; and share information with other entities in the State responsible for investigating critical incidents.

i. One Time Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the one-time requirements related to proposed §441.302(a)(6), we estimate it would take: 120 hours at \$108.68/hr for an administrative services manager to draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 20 hours at \$96.66/hr for a management analyst to update provider manuals; 80 hours at \$65.02/hr for a training and development specialist to develop and conduct training for providers; 80 hours at \$76.20/hr for a business operations specialist to establish processes for information sharing with other entities; 80 hours at \$100.80/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; 24 hours at \$110.82/hr for a general and operations manager to review and approve managed care contract modifications, policy and rules for publication, and training materials; and 10 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this requirement.

In aggregate, we estimate a one-time burden of 19,872 hours (414 hr x 48 States) at a cost of \$1,874,125 (48 States x [(120 hr x \$108.68/hr) + (20 hr x \$96.66/hr) + (80 hr x \$65.02/hr) + (80 hr x \$76.20/hr) + (80 hr x \$100.80/hr) + (24 hr x \$110.82/hr) + (10 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$937,063 ($$1,874,125 \times 0.50$).

In addition, we estimate that States, based on the results of the incident management system assessment discussed earlier in section II.B.3. of this preamble, that 82 percent of States, or 39 States (48 States x 0.82), would need to update existing electronic incident management

systems, while the remaining 9 States would need to implement new electronic incident management systems, to meet the proposed requirement at § 441.302(a)(6)(i)(B). We estimate based on information reported by some States in spending plans for section 9817 of the American Rescue Plan Act of 2021 that the cost per State to update existing electronic systems is \$2 million while the cost per State to implement new electronic systems is \$5 million.²⁴⁰ In aggregate, we estimate a one-time technology burden of \$123,000,000 [(\$2,000,000 x 39 States) + (\$5,000,000 x 9 States)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$61,500,000 (\$123,000,000 x 0.50).

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²⁴⁰ Enhanced Federal Financial Participation (FFP) is available at a 90 percent Federal Medical Assistance Percentage (FMAP) rate for the design, development, or installation of improvements of mechanized claims processing and information retrieval systems, in accordance with applicable Federal requirements. Enhanced FFP at a 75 percent FMAP rate is also available for operations of such systems, in accordance with applicable Federal requirements. However, the receipt of these enhanced funds is conditioned upon States meeting a series of standards and conditions to ensure investments are efficient and effective. As a result, we do not assume for the purpose of this burden estimate that States will qualify for the enhanced Federal match. This estimate overestimates State burden to the extent that States qualify for the enhanced Federal match.

TABLE 7: Summary of One-Time Burden for States for the Incident Management System Requirements (§ 441.302(a)(6))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage	Total Cost (\$)	State Share (\$)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans	48	48	Once	120	5,760	\$108.68/hr	\$625,997	\$312,998
Update provider manuals	48	48	Once	20	960	\$96.66/hr	\$92,794	\$46,397
Develop and conduct training for providers	48	48	Once	80	3,840	\$65.02/hr	\$249,677	\$124,838
Establish processes for information sharing with other entities	48	48	Once	80	3,840	\$76.20/hr	\$292,608	\$146,304
Build, design, and implement reports for using claims and other data to identify unreported incidents	48	48	Once	80	3,840	\$100.80/hr	\$387,072	\$193,536
Review and approve managed care contract modifications, policy and rules for publication, and training materials at the management level	48	48	Once	24	1,152	\$110.82/hr	\$127,665	\$63,832
Review and approve all operations associated with this requirement at the executive level	48	48	Once	10	480	\$204.82/hr	\$98,314	\$49,157
Subtotal Labor-Related Burden	48	336	Once	Varies	19,872	Varies	\$1,874,125	\$937,063
Update existing electronic incident management systems	39	39	Once	n/a	n/a	\$2,000,000/ system	\$78,000,000	\$39,000,000
Implement new electronic systems	9	9	Once	n/a	n/a	\$5,000,000/ system	\$45,000,000	\$22,500,000
Subtotal Non-Labor Burden	48	48	Once	n/a	n/a	Varies	\$123,000,000	\$61,500,000
TOTAL	48	384	Once	414	19,872	Varies	\$124,874,125	\$62,437,063

ii. Ongoing Incident Management System Requirements: States (§ 441.302(a)(6))

With regard to the ongoing requirements § 441.302(a)(6), we estimate that there are 0.5 critical incidents annually²⁴¹ for each of the 1,889,640 Medicaid beneficiaries who receive HCBS

²⁴¹ Data on the number of critical incidents is limited. We base our estimate on available public information, such as https://oig.hhs.gov/oas/reports/region7/1806081.pdf and https://dhs.sd.gov/servicetotheblind/docs/2015%20CIR%20Annual%20Trend%20Analysis.pdf.

under sections 1915(c), (i), (j), or (k) authorities annually, or 944,820 (1,889,640 x 0.5) critical incidents annually.²⁴² We further estimate that, based on data on unreported incidents, these requirements will result in the identification of 30 percent more critical incidents annually, or 283,446 (944,820 x 0.3) critical incidents;²⁴³ that 76 percent, or 215,419 (283,446 x 0.76) will be reported for individuals enrolled in FFS delivery systems;²⁴⁴ and that 10 percent of those for individuals enrolled in FFS delivery systems $(21,542 = 215,419 \times 0.1)$ will be made through provider reports and 90 percent ($193,877 = 215,419 \times 0.9$) through claims identification and other sources.²⁴⁵ We estimate 0.166 hr or 10 minutes at \$34.56/hr for a data entry worker to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. In aggregate, we estimate an ongoing burden each year of 3,576 hours (21,542 incidents x 0.166 hr) at a cost of \$123,587 (3,576 hr x \$34.56/hr) to record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems. While States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting critical incidents and identification of critical incidents through claims and other data sources to managed care entities and that the managed care entities would be responsible for reporting the identified critical incidents to the State.²⁴⁶ We further assume that the information reported by managed care entities to the State and identified by the State through claims and other data sources would be in an electronic form. For the 68,027 more critical incidents for individuals enrolled in managed care (283,446 more critical incidents identified x 24 percent for individuals enrolled in managed care), and the

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²⁴² https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.

²⁴³ Data on the number of unreported critical incidents is limited. We base our estimate on available public information, such as https://pennlive.com/news/2020/01/possible-abuse-of-group-home-residents-wasnt-adequately-tracked-in-pa-federal-audit.html and https://www.kare11.com/article/news/local/federal-audit-finds-maine-dhhs-failed-to-investigate-multiple-deaths-critical-incidents/97-463258015.

²⁴⁴ https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.

²⁴⁵ Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of more critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

²⁴⁶ Addressing Critical Incidents in the MLTSS Environment: Research Brief, ASPE, https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.

193,877 more critical incidents identified through claims and other data sources for individuals enrolled in FFS (283,446 more critical incidents identified x 76 percent for individuals enrolled in FFS x 90 percent identified through claims and other sources), we estimate 2 minutes (0.0333 hr) at \$34.56/hr for a data entry worker to record the information on each of these 261,904 critical incidents (68,027 + 193,877). In aggregate, for § 441.302(a)(6), we estimate an ongoing annual burden of 8,721 hours (261,904 incidents x 0.0333 hr) at a cost of \$301,398 (8,721 hr x \$34.56/hr) on these critical incidents.

In total, for § 441.302(a)(6), we estimate an ongoing burden each year of 12,297 hours (3,576 hours + 8,721 hours) at a cost of \$424,985 (\$123,587 + \$301,398) to record the information on all critical incidents for individuals enrolled in FFS and managed care delivery systems across all States. We further estimate it would take 12 hours at \$76.20/hr for a business operations specialist to maintain processes for information sharing with other entities; 20 hours at \$100.80/hr for a computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents; 24 hours at \$110.82/hr for a general and operations manager to monitor the operations associated with this requirement; and 4 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement in each State. In aggregate, we estimate an ongoing burden of 15,177 hours ([60 hr x 48 States] + 12,297 hr) at a cost of \$732,617 (\$424,985 + [48 States x ((12 hr x \$76.20/hr) + (20 hr x \$100.80/hr) + (24 hr x \$110.82/hr) + 4 hr x \$204.82/hr)]). In addition, we estimate an on-going annual technology-related cost of \$500,000 per State for States to maintain their electronic incident management systems. In aggregate, we estimate an ongoing burden of \$24,000,000 (\$500,000 x 48 States) for States to maintain their electronic incident management systems. In total, we estimate an ongoing annual burden of 15,177 hours at a cost \$24,732,617 (\$732, 617 + \$24,000,000). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$12,366,309

(\$24,732,617 x 0.50). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$12,366,309 (\$24,732,617 x 0.50).

TABLE 8: Summary of Ongoing Burden for States for the Incident Management System Requirements at Proposed § 441.302(a)(6)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage	Total Cost (\$)	State Share (\$)
Record the information on each reported critical incident reported by providers for individuals enrolled in FFS delivery systems	48	21,542	Annually	0.166	3,576	34.56/hr	123,587	61,793
Record the information on critical incidents for individuals enrolled in managed care and critical incidents identified through claims and other data sources for individuals enrolled in FFS	48	261,904	Annually	0.033	8,721	34.56/hr	301,398	150,699
Maintain processes for information sharing with other entities	48	48	Annually	12	576	76.20/hr	43,891	21,946
Update and maintain reports for using claims and other data to identify unreported incidents	48	48	Annually	20	960	100.80/hr	96,768	48,384
Monitor operations associated with this requirement at the management level	48	48	Annually	24	1,152	110.82/hr	127,664.64	63,832
Review and approve all operations associated with this collection of information requirement at the executive level	48	48	Annually	4	192	204.82/hr	39,325.44	19,662.72
Subtotal: Labor Related Burden	48	283,638	Annually	Varies	15,177	Varies	732,634	366,317
Maintain electronic incident management systems (specifically, § 441.302(a)(6)(i)(B))	48	48	Annually	n/a	n/a	500,000/ system	24,000,000	12,000,000
Total Technology Cost	48	48	Annually	n/a	n/a	500,000/ system	24,000,000	12,000,000

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage	Total Cost (\$)	State Share (\$)	
TOTAL	48	283,638	Annually	Varies	15,177	Varies	24,732,634	12,366,317	

b. Service Providers and Managed Care Contractors

The burden associated with this proposed rule would affect service providers that provide HCBS under sections 1915(c), (i), (j), and (k) authorities, as well as managed care entities that contract with the States to provide managed long-term services and supports.

The following discussion estimates an ongoing burden for service providers to implement these requirements and both a one-time and ongoing burden for managed care contractors.

i. On-going Incident Management System Requirements: Service Provider

To estimate the number of service providers that would be impacted by this proposed rule, we used unpublished data from the Provider Relief Fund to estimate that there are 19,677 providers nationally across all payers delivering the types of HCBS that are delivered under sections 1915(c), (i), (j), and (k) authorities. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (19,677 providers nationally x 48 States subject to the proposed requirement / 51 States = 18,520 providers). We used data from the Centers for Disease Control and Prevention²⁴⁷ to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 14,446 providers impacted (18,520 providers x 0.78), while at a high end of 85 percent participation, we estimate that there are 15,742 providers impacted (18,520 providers x 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

²⁴⁷ https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf.

As discussed earlier, we estimate that providers will report 10 percent, or 28,345, of the more critical incidents (283,446 more critical incidents x 0.10) identified annually as a result of these requirements. Based on these figures, we estimate that, on average, each provider will report 1.8 (28,345 incidents / 15,742 providers) more critical incidents annually. We further estimate that, on average, it would take a provider 1 hour at \$110.82/hr for a general and operations manager to collect the required information and report the information to the State or to the managed care entity as appropriate for each incident.²⁴⁸ In aggregate, for § 441.302(a)(6), we estimate an ongoing burden of 28,345 hours (28,345 incidents x 1 hr) at a cost of \$3,141,193 (28,345 hr x \$110.82/hr).

TABLE 9: Summary of Ongoing Burden for Service Providers for the Incident Management System Requirements

Requirement	No. Respondents	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect the required information and report the information to the State or to the managed care entity (§ 441.302(a)(6)(i)(C))	15,742 providers	28,345 incidents	Annually	1	28,345	110.82	3,141,193	n/a
Total	15,742 providers	28,345 incidents	Annually	1	28,345	110.82	3,141,193	n/a

ii. One Time Incident Management System Requirements: Managed Care Entities (§ 441.302(a)(6))

As required under proposed § 441.302(a)(6), while States can establish different processes for the reporting of critical incidents for individuals enrolled in managed care, we assume for the purpose of this analysis that the States would delegate provider reporting of critical incidents and identification of critical incidents through claims and other data sources to

²⁴⁸ The actual amount of time for each incident will vary depending on the nature of the critical incident and the specific reporting requirements of each State and managed care entity. This estimate assumes that some critical incidents will take substantially less time to report, while others could take substantially less time.

managed care entities and that the managed care entities would be responsible for reporting the identified critical incidents to the State.²⁴⁹ We further assume that the information reported by managed care entities to the State would be in an electronic form.

We estimated that there are 161 managed long-term services and supports plans providing services across 25 States.²⁵⁰ With regard to the one-time requirements at § 441.302(a)(6), we estimate it would take: 20 hours at \$108.68/hr for an administrative services manager to draft policy for contracted providers; 20 hours at \$96.66/hr for a management analyst to update provider manuals; 40 hours at \$65.02/hr for a training and development specialist to develop and conduct training for providers; 80 hours at \$100.80/hr for a computer and information analyst to build, design, and implement reports for using claims and other data to identify unreported incidents; and 6 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 26,726 hours (161 managed care entities x 166 hr) at a cost of \$2,576,084 (161 managed care entities x [(20 hr x \$108.68/hr) + (20 hr x \$96.66/hr) + (40 hr x \$65.02/hr) + (80 hr x \$100.80/hr) + (6 hr x \$204.82/hr)]).

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²⁴⁹ Addressing Critical Incidents in the MLTSS Environment: Research Brief, available at https://aspe.hhs.gov/reports/addressing-critical-incidents-mltss-environment-research-brief-0.

²⁵⁰ "A View from the States: Key Medicaid Policy Changes: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2019 and 2020," https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/.

TABLE 10: Summary of One-Time Burden for Managed Care Entities (MCEs) for the Incident Management System Requirements at § 441.302(a)(6)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Shar e (\$)
Draft policy for contracted providers	161	161	Once	20	3,220	108.68	349,950	n/a
Update provider manuals	161	161	Once	20	3,220	96.66	311,245	n/a
Develop and conduct training for providers	161	161	Once	40	6,440	65.02	418,729	n/a
Build, design, and implement reports for using claims and other data to identify unreported incidents	161	161	Once	80	12,880	100.80	1,298,304	n/a
Review and approve all operations associated with this requirement	161	161	Once	6	966	204.82	197,856	n/a
Total	161	805	Once	Varies	26,726	Varies	2,576,084	n/a

iii. Ongoing Incident Management System Requirements: Managed Care Entities (§ 441.302(a)(6))

The on-going burden to managed care entities consists of the collection and maintenance of information on critical incidents. As noted earlier, we estimate that these requirements will result in the identification of 283,446 more critical incidents annually than are currently identified by States. We further estimate that 24 percent, or 68,027 (283,446 x 0.24), will be reported for individuals enrolled in managed care delivery systems²⁵¹ and that 10 percent, or 6,803 (68,027 x 0.10), will be made through provider reports and 90 percent, or 61,224 (68,027 x 0.90), through claims identification and other sources.²⁵² We estimate that it would take 0.166 hr at \$34.56/hr for a data entry worker to record the information on each reported critical incident reported by providers (§ 441.302(a)(6)(i)(B)(2)). In aggregate, we estimate an ongoing burden of 1,129 hours (6,803 critical incidents made through provider reports x 0.166 hr) at a cost of \$39,018 (1,129 hr x \$34.56/hr). We also estimate that it would take: 20 hours at \$100.80/hr for a

²⁵¹ https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-user-brief-2019.pdf.

²⁵² Data is limited on the identification of critical incidents through various data sources. We conservatively assume that 25 percent of additional critical incidents identified as a result of these requirements will be reported by providers even though claims data will likely identify a substantially higher of percentage of claims than will be reported by providers.

computer and information analyst to update and maintain reports for using claims and other data to identify unreported incidents (§ 441.302(a)(6)(i)(B)(3)); 6 hours at \$110.82/hr for a general and operations manager to monitor the operations associated with this requirement and report the information to the State (§ 441.302(a)(6)(i)(E)); and 1 hour at \$204.82/hr for a chief executive to review and approve all operations associated with this collection of information requirement (§ 441.302(a)(6)(i)(G)). In aggregate, we estimate an ongoing burden of 5,476 hours (1,129 hr + [161 managed care entities x 27 hr]) at a cost of \$503,622 (\$39,018 + (161 managed care entities x (20 hr x \$100.80/hr) + (6 hr x \$110.82/hr) + (1 hr x \$204.82/hr)]).

TABLE 11: Summary of Ongoing Burden for Managed Care Entities (MCEs) for the Incident Management System Requirements

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Record the information on each reported critical incident reported by providers (§441.302(a)(6)(i)(B) (2))	161	6,803	Annually	0.166	1,129	34.56	39,029	n/a
Update and maintain reports for using claims and other data to identify unreported incidents (§441.302(a)(6)(i)(B) (3))	161	161	Annually	20	3,220	100.80	324,576	n/a
Monitor the operations associated with this requirement and report the information to the State (§441.302(a)(6)(i)(E))	161	161	Annually	6	966	110.82	107,052	n/a
Review and approve all operations associated with this requirement (§441.302(a)(6)(i)(G)	161	161	Annually	1	161	204.82	32,976	n/a
Total	161	7,286	Annually	Varies	5,476	Varies	503,633	n/a

5. ICRs Regarding HCBS Payment Adequacy (§§ 441.302(k) and 441.311(e); cross-referenced to §§ 441.464(f), 441.570(f) and 441.745(a)(1)(iv), and part 438)

This proposed rule would update § 441.302, by adding new paragraph (k)(2), which would require that at least 80 percent of Medicaid payments for the following services be spent on compensation, as defined at § 441.302(k)(1)(i), to direct care workers for the following services: homemaker services, home health aide services, and personal care services.

Proposed § 441.302(k)(1)(i) defines compensation to include salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 et seq., 29 CFR parts 531 and 778); benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and the employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act. Proposed § 441.302(k)(1)(ii) defines direct care workers to include workers who provide nursing services, assist with activities of daily living (such as mobility, personal hygiene, eating), or provide support with instrumental activities of daily living (such as cooking, grocery shopping, managing finances). Specifically, direct care workers include nurses (registered nurses, licensed practical nurses, nurse practitioners, or clinical nurse specialists) who provide nursing services to Medicaid-eligible individuals receiving HCBS, licensed or certified nursing assistants, direct support professionals, personal care attendants, home health aides, and other individuals who are paid to directly provide services to Medicaid beneficiaries receiving HCBS to address activities of daily living or instrumental activities of daily living. Direct care workers include individuals employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider. State agency, or third party; or delivering services under a self-directed service model.

To demonstrate compliance with the requirements proposed at § 441.302(k), new reporting requirements are proposed at § 441.311(e). Specifically, States would be required to report separately on the percent of payments that are spent on the direct care workforce for HCBS services. The services are found at § 440.180(b)(2) through (4), and include: homemaker services, home health aide services, and personal care services. Separate reporting would be required on payment for services that are self-directed.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. States

The burden associated with the proposed requirements would affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. 253,254 We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, under proposed §§ 441.302(k) and 441.311(e), States would have to: (1) draft new policy (one-time); (2) publish the provider requirements through State notice and publication processes (one-time); (3) update provider manuals and other policy guidance for each of the services subject to the requirement (one-time); (4) inform providers of services through State notification processes, both initially and annually (one-time and ongoing); (5) collect the information from providers for each service required (ongoing); (6) aggregate the data broken down by each service as well as self-directed services (ongoing); (7) derive an overall percentage for each service including self-directed services (ongoing); and (8) report to us on an annual basis (ongoing).

²⁵³ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

²⁵⁴ For purposes of this burden analysis, we are not taking into consideration temporary wage increases or bonus payments that have been or are being made.

i. One Time HCBS Payment Adequacy Requirements: State Burden

With regard to the one-time requirements, we estimate it would take: 80 hours at \$108.68/hr for an administrative services manager to: draft policy content, prepare notices and draft rules for publication, conduct public hearings, and draft contract modifications for managed care plans; 30 hours at \$96.66/hr for a management analyst to update provider manuals for each of the affected services, and draft provider agreement amendments; 25 hours at \$92.92/hr for a computer programmer to build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice; 60 hours at \$65.02/hr for a training and development specialist to develop and conduct training for providers; 6 hours at \$110.82/hr for a general and operations manager to: review, approve managed care contract modifications, policy and rules for publication, and training materials; and 3 hours at \$204.82/hr for a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate a one-time burden of 9,792 hours (204 hr x 48 States) at a cost of \$916,693 (48 States x [(80 hr x \$108.68/hr) + (30 hr x \$96.66/hr) + (25 hr x 92.92/hr + (60 hr x 65.02/hr) + (6 hr x 110.82/hr) + (3 hr x 204.82/hr). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$458,347 (\$916,693 x 0.50).

TABLE 12: Summary of One-Time Burden for States for the HCBS Payment Adequacy Requirements at §§ 441.302(k) and 441.311(e)

	No. Respondent	Total Response	Frequenc	Time per Response	Total Time	Wage	Total	State Share
Requirement	S	S	y	(hr)	(hr)	(\$/hr)	Cost (\$)	(\$)
Draft policy content, prepare notices and draft rules for publication, conduct public hearings; and draft contract modifications for managed care plans	48	48	Once	80	3,840	108.68	417,331	208,666
Update provider manuals for each of the affected services, draft provider agreement amendment	48	48	Once	30	1,440	96.66	139,190	69,595
Build, design, and operationalize internal systems for collection, aggregation, stratification by service, reporting, and creating remittance advice	48	48	Once	25	1,200	92.92	111,504	55,752
Develop and conduct training for providers	48	48	Once	60	2,880	65.02	187,258	93,629
Review, approve managed care contract modifications, policy and rules for publication, and training materials	48	48	Once	6	288	110.82	31,916	15,958.0 8
Review and approve all operations associated with this requirement	48	48	Once	3	144	204.82	29,494	14,747
Total	48	288	Once	Varies	9,792	varies	916,693	458,347

ii. Ongoing HCBS Payment Adequacy Requirements: State Burden

With regard to the on-going requirements, we estimate it would take 6 hours at \$92.92/hr for a computer programmer to: (1) collect the information from all providers for each service required; (2) aggregate and stratify by each service as well as self-directed services; (3) derive an overall percentage for each service including self-directed services; and (4) develop report to CMS on an annual basis. We also estimate it would take 2 hours at \$110.82/hr by a general and operations manager to review, verify, and approve reporting to CMS and 1 hour at \$204.82/hr for

a chief executive to review and approve all operations associated with this requirement. In aggregate, we estimate an ongoing burden of 432 hours (9 hr x 48 States) at a cost of \$47,231 (48 States x [(6 hr x \$92.92/hr) + (2 hr x \$110.82/hr) + (1 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$23,616 (\$47,231 x 0.50) per year.

TABLE 13: Summary of Ongoing Burden for States for the HCBS Payment Adequacy Requirements at §§ 441.302(k) and 441.311(e)

Requirement	No. Respondent s	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect information from providers; aggregate and stratify data as required; derive an overall percentage for each service; and develop report annually	48	48	Annually	6	288	92.92	26,761	13,380
Review, verify and approve reporting to CMS	48	48	Annually	2	96	110.82	10,639	5,319
Review and approve all operations associated with this requirement	48	48	Annually	1	48	204.82	9,831	4,916
Total	48	144	Annually	Varies	432	Varies	47,231	23,616

b. Service Providers and Managed Care Contractors

The burden associated with this proposed rule will affect both service providers that provide the services listed at § 440.180(b)(2) through (4) across HCBS programs as well as managed care entities that contract with the States to provide managed long-term services and supports. We estimate both a one-time and ongoing burden to implement the reporting requirements § 441.311(e) for both service providers and managed care contractors.

To estimate the number of service providers that will be impacted by this proposed rule, we used unpublished data from the Provider Relief Fund to estimate that there are 14,444 providers nationally across all payers delivering homemaker, home health aide, and/or personal care services. We then prorate the number to estimate the number of providers in the 48 States that are subject to this requirement (14,444 providers nationally x 48 States subject to the

proposed requirement / 51 States = 13,594 providers). We used data from the Centers for Disease Control and Prevention²⁵⁵ to estimate the percentage of these HCBS providers that participate in Medicaid and, due to uncertainty in the data and differences in provider definitions, estimate both a lower and upper range of providers affected. At a low end of 78 percent Medicaid participation, we estimate that there are 10,603 providers impacted (13,594 x 0.78), while at a high end of 85 percent participation, we estimate that there are 11,555 providers impacted (13,594 x 0.85). To be conservative and not underestimate our projected burden analysis, we are using the high end of our estimates to score the PRA-related impact of the proposed requirements.

i. One Time HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the one-time requirements, we estimate it would take: 35 hours at \$70.98/hr for a compensation, benefits and job analysis specialist to calculate compensation, as defined by § 441.302(k)(1)(i) for each direct care worker defined at § 441.302(k)(1)(ii); 40 hours at \$92.92/hr for a computer programmer to build, design and operationalize an internal system to calculate each direct care worker's compensation as a percentage of total revenues received, aggregate the sum of direct care worker compensation as an overall percentage, and separate self-directed services to report to the State; and 8 hours at \$110.82/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 959,065 hours (11,555 providers x 83 hr) at a cost of \$81,897,911 (11,555 providers x [(35 hr x \$70.98/hr) + (40 hr x \$92.92/hr) + (8 hr x \$110.82/hr)]).

TABLE 14: Summary of One-Time Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost	State Shar e (\$)
Calculate compensation for each direct care worker	11,555	11,555	Once	35	404,425	70.98	28,706,087	n/a
Build, design and operationalize an internal system for reporting to the State	11,555	11,555	Once	40	462,200	92.92	42,947,624	n/a
Review and approve reporting to the State	11,555	11,555	Once	8	92,440	110.82	10,244,200	n/a
Total	11,555	34,665	Once	Varies	959,065	varies	81,897,911	n/a

ii. Ongoing HCBS Payment Adequacy Requirements: Service Providers (§ 441.311(e))

With regard to the on-going requirements, we estimate it would take 8 hours at \$70.98/hr for a compensation, benefits, and job analysis specialist to account for new hires and/or contracted employees; 8 hours at \$92.92/hr for a computer programmer to calculate compensation, aggregate data, and report to the State as required; and 5 hours at \$110.82/hr for a general and operations manager to review and approve reporting to the State. In aggregate, we estimate an on-going burden of 242,655 hours (11,555 providers x 21 hr) at a cost of \$21,553,542 (11,555 providers x [(8 hr x \$70.98/hr) + (8 hr x \$92.92/hr) + (5 hr x \$110.82/hr)]).

TABLE 15: Summary of Ongoing Burden for Service Providers for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost	State Shar e (\$)
Account for new hires and/or contracted employees	11,555	11,555	Once	8	92,440	70.98	6,561,391	n/a
Calculate compensation, aggregate data, and report to the State	11,555	11,555	Once	8	92,440	92.92	8,589,525	n/a
Review and approve reporting to the State	11,555	11,555	Once	5	57,775	110.82	6,402,626	n/a
Total	11,555	34,665	Once	Varies	242,655	varies	21,553,542	n/a

iii. One time HCBS Payment Adequacy Requirements: Managed Care Entities (§ 441.311(e))

As noted earlier, the burden associated with this proposed rule will affect managed care entities (see section d, below) that contract with the States to provide managed long-term services and supports. We estimate that there are 161 managed long-term services and supports plans providing services across 25 States.²⁵⁶ We estimate both a one-time and ongoing burden for managed care entities to implement these requirements. Specifically, managed care entities would have to: (1) draft new policy (one-time); (2) update provider manuals for each of the services subject to the requirement (one-time); (3) inform providers of requirements (one-time and ongoing); (4) collect the information from providers for each service required (ongoing); (5) aggregate the data as required by the States (ongoing); and (6) report to the State on an annual basis (ongoing).

With regard to the one-time requirements, we estimate it would take 40 hours at \$108.68/hr for an administrative services manager to draft policy for contracted providers; 25 hours at \$92.92/hr for a computer programmer to build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting; 30 hours at \$65.02/hr for a training and development specialist to develop and conduct training for

²⁵⁶ https://www.kff.org/report-section/a-view-from-the-states-key-medicaid-policy-changes-long-term-services-and-supports/; Profiles & Program Features | Medicaid.

providers; and 3 hours at \$204.82/hr for a chief executive to review and approve reporting to the State. In aggregate, we estimate a one-time burden of 15,778 hours (161 MCEs x 98 hr) at a cost of \$1,486,877 (161 MCEs x [(40 hr x \$108.68/hr) + (25 hr x \$92.92/hr) + (30 hr x \$65.02/hr) + (3 hr x \$204.82/hr)]).

TABLE 16: Summary of One-time Burden for Managed Care Entities (MCEs) for the HCBS Payment Adequacy Requirements at § 441.311(e)

	No. Respondent	Total Response	Frequenc	Time per Response	Total Time	Wage	Total Cost	State Shar
Requirement	S	s	y	(hr)	(hr)	(\$/hr)	(\$)	e (\$)
Draft policy for contracted providers	161	161	Once	40	6,440	108.68	699,899	n/a
Build, design, and operationalize internal systems for data collection, aggregation, stratification by service, and reporting	161	161	Once	25	4,025	92.92	374,003	n/a
Develop and conduct training for providers	161	161	Once	30	4,830	65.02	314,047	n/a
Review and approve reporting to the State	161	161	Once	3	483	204.82	98,928	n/a
Total	161	644	Once	Varies	15,778	varies	1,486,877	n/a

iv. Ongoing HCBS Payment Adequacy Requirements: Managed Care Entities (§ 441.311(e))

With regard to the ongoing requirements, we estimate it would take: 6 hours at \$92.92/hr for a computer programmer to: (1) collect the information from all providers for each service required, (2) aggregate and stratify data as required, and (3) develop report to the State on an annual basis; and 2 hours at \$204.82/hr for a chief executive to review and approve the reporting to the State. In aggregate, we estimate an ongoing burden of 1,288 hours (161 MCEs x 8 hr) at a cost of \$155,713 (161 MCEs x [(6 hr x \$92.92/hr) + (2 hr x \$204.82/hr)]).

TABLE 17: Summary of Ongoing Burden for Managed Care Entities (MCEs) for the HCBS Payment Adequacy Requirements at § 441.311(e)

Requirement	No. Respondent s	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Collect information from providers; aggregate and stratify data as required; and develop report annually	161	161	Annually	6	966	92.92	89,760	n/a
Review and approve the report	161	161	Annually	2	322	204.82	65,952	n/a
Total	161	322	Annually	Varies	1,288	varies	155,713	n/a

6. ICRs Regarding Supporting Documentation for HCBS Access (§§ 441.303(f)(6) and 441.311(d)(1))

Section 1915(c) of the Act authorizes States to set enrollment limits or caps on the number of individuals served in a waiver, and many States maintain waiting lists of individuals interested in receiving waiver services once a spot becomes available. States vary in the way they maintain waiting lists for section 1915(c) waivers, and if a waiting list is maintained, how individuals may join the waiting list. Some States permit individuals to join a waiting list as an expression of interest in receiving waiver services, while other States require individuals to first be determined eligible for waiver services to join the waiting list. States have not been required to submit any information on the existence or composition of waiting lists, which has led to gaps in information on the accessibility of HCBS within and across States. Further, feedback obtained during various interested parties' engagement activities conducted with States and other interested parties over the past several years about reporting requirements for HCBS, as well as feedback received through the RFI²⁵⁷ discussed earlier, indicate that there is a need to improve public transparency and processes related to States' HCBS waiting lists.

²⁵⁷ CMS Request for Information: Access to Coverage and Care in Medicaid & CHIP. February 2022. For a full list of question from the RFI, see https://www.medicaid.gov/medicaid/access-care/downloads/access-rfi-2022-questions.pdf.

We propose to amend § 441.303(f)(6) by adding language to the end of the regulatory text: "If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1)."

For States that limit or cap enrollment in a section 1915(c) waiver and maintain a waiting list, States would be required to provide a description annually on how they maintain the list of individuals who are waiting to enroll in a section 1915(c) waiver program. The description must include, but not be limited to, information on whether the State screens individuals on the waiting list for eligibility for the waiver program, whether the State periodically re-screen individuals on the waiver list for eligibility, and the frequency of re-screening, if applicable. In addition, States would be required to report of the number of people on the waiting list if applicable, as well as the average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the waiting list, if applicable.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both **Federal Register** notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

a. One Time Waiting List Reporting Requirements: States (§ 441.311(d)(1))

The one-time State burden associated with the waiting list reporting requirements proposed in § 441.311(d)(1) will affect the 39 State Medicaid programs with waiting lists for section 1915(c) waivers.²⁵⁸ We estimate both a one-time and ongoing burden to implement these requirements at the State level. Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the number of people on existing waiting lists and how long they wait; and write or update their existing waiting list policies and the information collected. In some States, HCBS waivers are administered by more than one operating agency, in these cases each will have to report this data up to the Medicaid agency for submission to us.

With regard to the one-time requirements, we estimate it would take: 16 hours at \$108.68/hr for an administrative services manager to write or update State policy, direct information collection, compile information, and produce a report; 20 hours at \$92.92/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at \$110.82/hr for a general and operations manager to review and approve report; and 2 hours at \$204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 1,599 hours (39 States x 41 hr) at a cost of \$169,236 (39 States x [(16 hr x \$108.68/hr) + (20 hr x \$92.92/hr) + (3 hr x \$110.82/hr) + (2 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$84,618 (\$169,236 x 0.50).

Assuming no changes to the State waiting list policies, each year States would only need to update the report to reflect the number of people on the list of individuals who are waiting to enroll in the waiver program and average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list.

²⁵⁸ https://www.kff.org/report-section/state-policy-choices-about-medicaid-home-and-community-based-services-amid-the-pandemic-issue-brief/.

TABLE 18: Summary of One-Time Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Write or update State policy, direct information collection, compile information, and produce a report	39	39	Once	16	624	108.68	67,816	33,908
Query internal systems for reporting requirements	39	39	Once	20	780	92.92	72,478	36,239
Review and approve report at management level	39	39	Once	3	117	110.82	12,966	6,483
Review and approve all reports associated with this requirement at the executive level	39	39	Once	2	78	204.82	15,976	7,988
Total	39	156	Once	Varies	1,599	Varies	169,236	84,618

b. Ongoing Waiting List Reporting Requirements: States (§ 441.311(d)(1))

With regard to the on-going burden for the section 1915(c) waiver waiting list reporting requirements at § 441.311(d)(1), we estimate it would take: 4 hours at \$108.68/hr for an administrative services managers across relevant operating agencies to direct information collection, compile information, and produce a report; 6 hours at \$92.92/hr for a computer programmer or contractor to query internal systems for reporting requirements; 3 hours at \$110.82/hr for a general and operations manager to review and approve report; and 2 hours at \$204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 585 hours (39 States x 15 hr) at a cost of \$67,639 (39 States x [(4 hr x \$108.68/hr) + (6 hr x \$92.92/hr) + (3 hr x \$110.82/hr) + (2 hr x

\$204.82/hr)]. Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$33,820 (\$67,639 x 0.50) per year.

TABLE 19: Summary of Ongoing Burden for States for the Waiting List Reporting Requirements at § 441.311(d)(1)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	39	39	Annually	4	156	108.68	16,954	8,477
Query internal systems for reporting requirements	39	39	Annually	6	234	92.92	21,743	10,872
Review and approve report at the management level	39	39	Annually	3	117	110.82	12,966	6,483
Review and approve all reports associated with this requirement at the executive level	39	39	Annually	2	78	204.82	15,976	7,988
Total	39	156	Annually	Varies	585	Varies	67,639	33,820

7. ICRs Regarding Additional HCBS Access Reporting (§ 441.311(d)(2)(i))

Additional HCBS access reporting is proposed at § 441.311(d)(2)(i). States would be required to report annually on the average amount of time from when homemaker services, home health aide services, or personal care services, listed in § 440.180(b)(2) through (4), are initially approved to when services began for individuals newly approved to begin receiving services within the past 12 months. For this specific metric, States will be allowed to report on a statistically valid random sample of individuals newly approved to begin receiving these services within the past 12 months.

Proposed § 441.311(d)(2)(ii) would require States to report annually on the percent of authorized hours for homemaker services, home health aide services, or personal care, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. States will have the option to report on a statistically valid random sample of individuals authorized to receive these services within the past 12 months, rather than all individuals authorized to receive these within the past 12 months.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

The burden associated with the proposed additional HCBS access reporting requirements at § 441.311(d)(2) would affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities.²⁵⁹ Specifically, States will have to query their databases or instruct their contractors to do so to collect information on the average amount of time from which homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months, and the percent of authorized hours for these services that are provided within the past 12 months. We

²⁵⁹ Arizona, Rhode Island, and Vermont do not have HCBS programs under any of these authorities.

expect many States will need to analyze report this metric for a statistically valid random sample of beneficiaries. They will then need to produce a report for us within such information. For States with managed long-term services and supports, they would need to direct managed care entities to report this information up to them.

We estimate one-time and ongoing burden to implement the requirements at § 441.311(d)(2) at the State level.

a. One-Time HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the one-time burden related to the HCBS access reporting requirements, we estimate it would take: 20 hours at \$108.68/hr for an administrative services manager across relevant operating agencies to direct information collection, compile information, and produce a report; 60 hours at \$92.92/hr for a computer programmer or contractor to analyze service authorization and claims data; 40 hours at \$95.62/hr for a statistician to conduct data sampling; 3 hours at \$110.82/hr for a general and operations manager to review and approve report; and 2 hours at \$204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a one-time burden of 6,000 hours (48 States x 125 hr) at a cost of \$591,154 (48 States x [(20 hr x \$108.68/hr) + (60 hr x \$92.92/hr) + (40 hr x \$95.62/hr) + (3 hr x \$110.82/hr) + (2 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$295,577 (\$591,154 x 0.50) per year.

TABLE 20: Summary of One-Time Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	48	48	Once	20	960	108.68	104,333	52,166
Analyze service authorization and claims data	48	48	Once	60	2,880	92.92	267,610	133,805
Conduct data sampling	48	48	Once	40	1,920	95.62	183,590	91,795
Review and approve report at the management level	48	48	Once	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level	48	48	Once	2	98	204.82	19,663	9,831
Total	48	240	Once	Varies	6,000	Varies	591,154	295,577

b. Ongoing HCBS Access Reporting Requirements: States (§ 441.311(d)(2))

With regard to the on-going burden related to the HCBS access reporting requirements for States, we estimate it would take: 10 hours at \$108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report; 20 hours at \$92.92/hr for a computer programmer or contractor to analyze service authorization and claims data; 10 hours at \$95.62/hr for a statistician to conduct data sampling; 3 hours at \$110.82/hr for a general and operations manager to review and approve report; and 2 hours at \$204.82/hr for a chief executive to review and approve all reports associated with this requirement. In aggregate, we estimate a burden of 2,160 hours (48 States x 45 hr) at a cost of \$222,888 (48 States x [(10 hr x \$108.68/hr) + (20 hr x \$92.92/hr) + (10 hr x \$95.62/hr) + (3 hr x \$110.82/hr) + (2 hr x

\$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$111,444 (\$222,888 x 0.50) per year.

TABLE 21: Summary of Ongoing Burden for States for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report	48	48	Annually	10	480	108.68	52,166	26,083
Analyze service authorization and claims data	48	48	Annually	20	960	92.92	89,203	44,601
Conduct data sampling	48	48	Annually	10	480	95.62	45,898	22,949
Review and approve report at the management level	48	48	Annually	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	204.82	19,663	9,831
Total	48	240	Annual	Varies	2,160	Varies	222,888	111,444

c. One-Time HCBS Access Reporting Requirements: Managed Care Entities (§ 441.311(d)(2))

With regard to the one-time proposed HCBS access reporting requirements at § 441.311(d)(2) for managed care entities, we estimate it would take: 10 hours at \$108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 35 hours at \$92.92/hr for a computer programmer to analyze service authorization and claims data; 10 hours at \$95.62/hr for a statistician to conduct data sampling; and 2 hours at \$204.82/hr for a chief executive review and approval. In aggregate, we

estimate a one-time burden of 9,177 hours (161 MCEs x 57 hr) at a cost of \$918,479 (161 MCEs x [(10 hr x \$108.68/hr) + (35 hr x \$92.92/hr) + (10 hr x \$95.62/hr) + (2 hr x \$204.82/hr)]).

TABLE 22: Summary of One-Time Burden for Managed Care Entities for the HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report to the State	161	161	Once	10	1,610	108.68	174,975	n/a
Analyze service authorization and claims data	161	161	Once	35	5,635	92.92	523,604	n/a
Conduct data sampling	161	161	Once	10	1,610	95.62	153,948	n/a
Review and approve report	161	161	Once	2	322	204.82	65,952	n/a
Total	161	644	Once	Varies	9,177	Varies	918,479	n/a

d. Ongoing HCBS Access Reporting Requirements: Managed Care Entities (§ 441.311(d)(2))

With regard to the ongoing requirements associated with the annual collection, aggregation, and reporting the HCBS access measures at § 441.311(d)(2), we estimate it would require: 4 hours at \$108.68/hr for an administrative services manager to direct information collection, compile information, and produce a report to the State; 20 hours at \$92.92/hr for a computer programmer to analyze service authorization and claims data; 8 hours at \$95.62/hr for a statistician to conduct data sampling; and 2 hours at \$204.82/hr for a chief executive to review and approve. In aggregate, we estimate a burden of 5,474 hours (161 MCEs x 34 hr) at a cost of \$558,303 (161 MCEs x [(4 hr x \$108.68/hr) + (20 hr x \$92.92/hr) + (8 hr x \$95.62/hr) + (2 hr x \$204.82/hr)]).

TABLE 23: Summary of Ongoing Burden for Managed Care Entities (MCEs) for Additional HCBS Access Reporting Requirements at § 441.311(d)(2)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Direct information collection, compile information, and produce a report to the State	161	161	Annually	4	644	108.68	69,990	n/a
Analyze service authorization and claims data	161	161	Annually	20	3,220	92.92	299,202	n/a
Conduct data sampling	161	161	Annually	8	1,288	95.62	123,159	n/a
Review and approve report	161	161	Annually	2	322	204.82	65,952	n/a
Total	161	644	Annually	Varies	5,474	Varies	558,303	n/a

- 8. ICRs Regarding Compliance Reporting (§ 441.311(b))
- a. Ongoing Incident Management System Assessment Requirements: States (§ 441.311(b)(1)

Through proposed updates to § 441.311(b)(1), as described in proposed § 441.302(a)(6)), this proposed rulemaking aims to standardize CMS expectations and State reporting requirements to ensure that States operate and maintain an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. The proposed updates were informed by the responses to the HCBS Incident Management Survey (CMS-10692; OMB 0938-1362) recently released to States.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more

definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10692 (OMB control number 0938-1362). We estimate that the proposed reporting requirement at § 441.311(b)(1) would apply to the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. Some States employ the same incident management system across their waivers, while others employ an incident management system specific to each waiver and will require multiple assessments to meet the proposed requirements at § 441.311(b)(1). Based on the responses to the previously referenced survey, we are estimating that on average States will conduct assessments on two incident management systems, totaling approximately 96 unique required assessments (48 State Medicaid programs x 2 incident management system assessments per State). Because the requirements proposed by § 441.311(b)(1) would be required every 24 months, we estimate 48 assessments on an annual basis (96 unique assessments every 2 years). With regard to the ongoing requirements, we estimate that it would take 1.5 hours at \$73.84/hr for a social/community service manager to gather information and complete the required assessment; and 0.5 hours at \$110.82/hr for a general and operations manager to review and approve the assessment. In aggregate, we estimate an ongoing annual burden of 96 hours (48 States x 2 hr) at a cost of \$7,976 (48 States x [(1.5 hr x \$73.84/hr)+(0.5 hr x \$110.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$3,988 (\$7,976 x 0.50) per year.

TABLE 24: Summary of the Ongoing Burden for States for the Proposed Incident Management System Assessment Requirements at § 441.311(b)(1)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Gather information and complete the required assessment	48	48	Annually	1.5	72	73.84	5,316	2,658
Review and approve the assessment	48	48	Annually	0.5	24	110.82	2,660	1,330
Total	48	96	Annually	Varies	96	varies	7,976	3,988

b. Reporting on Critical Incidents (§ 441.311(b)(2)), Person-Centered Planning (§ 441.311(b)(3)), and Type, Amount, and Cost of Services (§ 441.311(b)(4))

This proposed rulemaking codifies existing compliance reporting requirements on Critical Incidents, Person-Centered Planning, and Type, Amount, and Cost of Services. This includes codifying minimum performance standards at § 441.311(b)(2) and (3) and making updates to critical incident and person-centered planning requirements previously described in 2014 guidance,²⁶⁰ and moving the existing requirement at § 441.302(h)(1) to report on type, amount, and cost of services to § 441.311(b)(4) as part of the new consolidated compliance reporting section at § 441.311.

This proposed rule would remove our currently approved burden and replace it with the burden associated with the proposed amendments to § 441.311(b)(2) through (4). In aggregate, the change would remove 11,132 hours (253 waivers x 44 hr) and \$860,281 (11,132 hr x \$77.28/hr for a business operations specialist). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost reduction would be minus \$430,140 (-\$860,281 x 0.50).

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 $^{^{260}\} https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative_0_71.pdf.$

TABLE 25: Summary of the Removal of Approved Ongoing Burden for Form 372(S) as a Result of the Proposed Requirements at § 441.311(b)(2) through (b)(4)

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Remove currently approved burden under control number 0938–0272 (CMS– 372(S))	48	253	Annually	(44)	(11,1 32)	77.28	(\$860,281)	(\$430,140)
Total	48	253	Annually	(44)	(11,1 32)	77.28	(\$860,281)	(\$430,140)

We expect to revise the Form CMS-372(S) and the form's instructions based on the proposed reporting requirements. The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS 0938– 0272 (CMS-372(S)). The proposed consolidated reporting requirements at § 441.311(b)(2) through (4) also assume that 48 States (including Washington DC) are required to submit the Form CMS-372(S) Report on an annual basis. However, a separate form would no longer be required for each of the 253 approved waivers currently in operation. We estimate a burden of 50 hours for a business operations specialist to draft each Form CMS-372(S) Report submission. The per response increase reflects the proposed increase to the minimum State quality performance level for person-centered planning (at proposed § 441.301(c)(3)(ii)) and critical incident reporting (at proposed § 441.302(a)(6)(ii)) from the 86 percent threshold established by the 2014 guidance to 90 percent in this proposed rule. This slight increase to the minimum

performance level will help ensure that States are sufficiently meeting all section 1915(c) waiver requirements but may also increase the evidence that some States may need to submit to document that appropriate remediation is being undertaken to resolve any compliance deficiencies. As a result, we now estimate a total of 50 hours for each Form CMS-372(S) Report submission, comprised of 30 hours of recordkeeping, collection and maintenance of data, and 20 hours of record assembly, programming, and completing the Form CMS-372(S) Report in the required format. We also estimate 3 hours at \$110.82/hr for a general and operations manager to review and approve the report to CMS; and 2 hours at \$204.82/hr for a chief executive to review and approve all reports associated with this requirement.

TABLE 26: Summary of the New Burden for Form 372(S) Annual Report on HCBS Waivers, Inclusive of Updates to Proposed § 441.311(b)(2) through (4)

Requiremen	No. Respondent	Total Response	Frequenc v	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Draft Form CMS 372(S) Report submission	48	48	Annually	50	2,400	77.28	185,472	92,736
Review and approve the report at the management level	48	48	Annually	3	144	110.82	15,958	7,979
Review and approve all reports associated with this requirement at the executive level	48	48	Annually	2	96	204.82	19,663	9,831
Total	48	144	Annually	Varies	2,640	varies	221,093	110,546

The net change resulting from reporting requirements on critical incidents, person-centered service planning, and type, amount, and cost of services, proposed by § 441.311(b)(2) through (4) is a burden decrease of 8,492 hours and \$319,594 (State share).

9. ICRs Regarding Reporting on the Home and Community-Based Services (HCBS) Quality Measure Set (§ 441.311(c))

a. States

At § 441.311(c), we propose to require that States report every other year on the HCBS Quality Measure Set, which is described in section II.B.8.of the preamble. The proposed reporting requirement would affect the 48 States (including Washington DC) that deliver HCBS under section 1915(c), 1915(i), 1915(j), and 1915(k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level.

As proposed at § 441.311(c), the data collection would include reporting every other year on all measures in the HCBS Quality Measure Set that are identified by the Secretary.²⁶¹ For certain measures which are based on data already collected by us, the State can elect to have the Secretary report on their behalf.

Under proposed § 441.312(c)(1)(iii), States would also be required to establish performance targets, subject to our review and approval, for each of the measures in the HCBS Quality Measure Set that are identified as mandatory for States to report or are identified as measures for which we will report on behalf of States, as well as to describe the quality improvement strategies that they will pursue to achieve the performance targets for those measures.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has

 $^{{\}it 261}~Available~at~{\it https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.}$

yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

i. One Time HCBS Quality Measure Set Requirements: States (§ 441.311(c))

This one-time burden analysis assumes that States must newly adopt one of the "experience of care" surveys cited in the HCBS Quality Measure Set: The Consumer Assessment of Healthcare Providers and Systems Home and Community-Based (HCBS CAHPS®) Survey, National Core Indicators®-Intellectual and Developmental Disabilities (NCI®-IDD), National Core Indicators-Aging and Disability (NCI-AD)TM, or Personal Outcome Measures (POM)® to fully meet the HCBS Quality Measures Set mandatory requirements. Currently most States use at least one of these surveys; however, States may need to use multiple "experience of care" surveys, depending on the populations served by the States' HCBS program and the particular survey instruments that States select to use, to ensure that all major population groups are assessed using the measures in the HCBS Quality Measure Set.

The estimate of one-time burden related to the effort associated with the proposed requirements is for the first year of reporting. It assumes that the Secretary will initially require 25 of the 97 measures currently included in the HCBS Quality Measure Set. The estimate disregards costs associated with the voluntary reporting of measures in the HCBS Quality Measure Set that are not yet mandatory, and voluntary stratification of measures ahead of the phase-in schedule, discussed later in this section.

Additionally, the Secretary will require stratification by demographic characteristics of 25 percent of the measures in the HCBS Quality Measure Set for which the Secretary has specified that reporting should be stratified 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations. The burden associated with stratifying data is considered in the ongoing cost estimate only. We anticipate

that certain costs will decline after the first year of reporting, but that some of the reduction will be supplanted with costs associated with stratifying data.

With regard to the one-time requirements at § 441.311(c) for reporting on the initial mandatory elements of the HCBS Quality Measure Set, we estimate that would take: 540 hours at \$108.68/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report; 40 hours at \$95.62/hr for a statistician to determine survey sampling methodology; 500 hours at \$62.20/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 200 hours at \$34.56/hr for a data entry worker to input the data; 60 hours at \$92.92/hr for a computer programmer to synthesize the data; and 5 hours at \$204.82/hr for a chief executive to verify, certify, and approve the report. In aggregate, we estimate a one-time burden of 64,560 hours (48 States x 1,345 hr) at a cost of \$5,141,918 (48 States x [(540 hr x \$108.68/hr) + (40 hr x \$95.62/hr) + (500 hr x \$62.20/hr) + (200 hr x \$34.56/hr) + (60 hr x \$92.92/hr) + (5 hr x \$204.82/hr)]) Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$2,570.959 (\$5,141,918 x 0.50).

TABLE 27: Summary of the One-Time Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Conduct project planning, administer and oversee survey administration, compile measures, establish and describe performance targets, describe quality improvement strategies, and produce a report	48	48	Once	5200	25,920	108.68	2,816,986	1,408,493
Determine survey sampling methodology	48	48	Once	40	1,920	95.62	183,590	91,795
Receive training in survey administration and administer an in- person survey	48	48	Once	500	24,000	62.20	1,492,800	746,400
Input data	48	48	Once	200	9,600	34.56	346,944	173,472
Synthesize data	48	48	Once	60	2,880	92.92	267,610	133,805
Verify, certify, and approve the report	48	48	Once	5	240	204.82	49,157	24,578
Total	48	288	Once	Varies	64,560	varies	5,141,918	2,570,959

ii. Ongoing HCBS Quality Measure Set Requirements: States (§ 441.311(c))

With regard to the ongoing burden of fulfilling proposed requirements at § 441.311(c), every other year, for reporting on mandatory elements of the HCBS Quality Measure Set, including data stratification by demographic characteristics, we estimate it would take: 520 hours at \$108.68/hr for administrative services managers to conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report; 80 hours at \$95.62/hr for a statistician to determine survey sampling methodology; 1,250 hours at \$62.20/hr for survey researcher(s) to be trained in survey administration and to administer an in-person survey; 500 hours at \$34.56/hr for a data entry worker to input the data; 100 hours at \$92.92/hr for a computer programmer to synthesize the data; and 5 hours at \$204.82/hr for a chief executive to verify, certify, and approve a State data submission to us. In aggregate, we estimate an ongoing burden of 117,840 hours

(48 States x 2,455 hr) at a cost of \$8,136,446 (48 States x [(520 hr x \$108.68/hr) + (80 hr x \$95.62/hr) + (1,250 hr x \$62.20/hr) + (500 hr x \$34.56/hr) + (100 hr x \$92.92/hr) + (5 hr x \$204.82/hr)]). Given that reporting is every other year, the annual burden would be 58,920 hours (117,840 hr/2 years) and \$4,068,223 (\$8,136,446/2 years). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$2,034,112 (\$4,068,223 x 0.50).

TABLE 28: Summary of the Ongoing Burden for States for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Conduct project planning, administer and oversee survey administration, compile measures, update performance targets and quality improvement strategy description, and produce a report	48	48	Every other year	520	24,960	108.68	2,712,653	1,356,326
Determine survey sampling methodology	48	48	Every other year	80	3,840	95.62	367,181	183,590
Receive training in survey administration and administer an in- person survey	48	48	Every other year	1,250	60,000	62.20	3,732,000	1,866,000
Input data	48	48	Every other year	500	24,000	34.56	867,360	433,680
Synthesize data	48	48	Every other year	100	4,800	92.92	446,016	223,008
Verify, certify, and approve the report	48	48	Every other year	5	240	204.82	49,157	24,578
Total	48	576	Every other year	Varies	235,680	Varies	8,174,366	4,087,183

b. HCBS Quality Measure Set Requirements: Beneficiary Experience Survey (§ 441.311(c))

State adoption of existing beneficiary experience surveys, contained in the HCBS Quality Measure Set, to fulfill the proposed mandatory reporting requirements would include a burden on beneficiaries. As proposed in the previous section, a State must newly adopt one of the "experience of care" surveys cited in the HCBS Quality Measure Set: The Consumer

Assessment of Healthcare Providers and Systems Home and Community Based (HCBS CAHPS®) Survey, National Core Indicators® Intellectual and Developmental Disabilities (NCI® IDD), National Core Indicators Aging and Disability (NCI AD)TM, or Personal Outcome Measures (POM)®.

With regard to beneficiary burden, we estimate it would take 45 minutes (0.75 hr) at \$20.71/hr for a Medicaid beneficiary to complete a survey every other year that will be used to derive one or more of the measures in the HCBS Quality Measure Set. At 1,000 beneficiaries/State and 48 States, we estimate an aggregate burden of 36,000 hours (1,000 beneficiary responses/State x 48 States x 0.75 hr/survey) at a cost of \$745,560 (36,000 hr x \$20.71/hr). Given that survey is every other year, the annual burden would be 18,000 hours (36,000 hr/2 years) and \$372,780 (\$745,560/2 years).

TABLE 29: Summary of Beneficiary Experience Survey Burden for the HCBS Quality Measure Set Requirements at § 441.311(c)

Requireme nt	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Complete beneficiary experience survey	48,000	24,000	Annually	0.75	18,000	20.71	372,780	n/a
Total	48,000	48,000	Every other Year	0.75	18,000	20.71	\$ 745,560	n/a

10. ICRs Regarding Website Transparency (§ 441.313; cross-referenced to §§ 441.486, 441.595, and 441.750, as well as part 438)

The proposed rule adds a new section, at § 441.313, titled, "Website Transparency, to promote public transparency related to the administration of Medicaid-covered HCBS under section 1915(c) of the Act." Specifically, at § 441.313(a), we propose to require States to operate a website that meets the availability and accessibility requirements at § 435.905(b) and that provides the data and information that States are required to report under the newly proposed reporting section at § 441.311. At § 441.313(a)(1), we propose to require that the data and information that States are required to report under § 441.311 be provided on one website, either

directly or by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that is authorized to provide services. At § 441.313(a)(2), we propose to require that the web page include clear and easy to understand labels on documents and links.

At § 441.313(a)(3), we propose to require that States verify the accurate function of the website and the timeliness of the information and links at least quarterly. At § 441.313(c), we propose to apply these requirements to services delivered under FFS or managed care delivery systems. At § 441.313(a)(4), we propose to require that States explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number. Further, we propose to apply the proposed requirements at § 441.313 to sections 1915(j), (k), and (i) State plan services by cross-referencing at §§ 441.486, 441.595, and 441.750, respectively.

The following proposed changes will be submitted to OMB for their approval after this proposed rule is finalized and our survey instrument has been developed. The survey instrument and burden will be made available to the public for their review under the standard non-rule PRA process which includes the publication of 60- and 30-day Federal Register notices. In the meantime, we are setting out our preliminary burden figures (see below) as a means of scoring the impact of this rule's proposed changes. The availability of the survey instrument and more definitive burden estimates will be announced in both Federal Register notices. The CMS ID number for that collection of information request is CMS-10854 (OMB control number 0938-TBD). Since this would be a new collection of information request, the OMB control number has yet to be determined (TBD) but will be issued by OMB upon their approval of the new collection of information request.

The burden associated with the website transparency requirements proposed at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We are requiring at § 441.313(c) to apply the website transparency requirements to services delivered under FFS or managed care delivery systems, and we propose to provide States with the option to meet the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. However, we are not requiring managed care entities to report the data and information required under § 441.311 on their website. As such, we estimate that there is no additional burden for managed care entities associated with the requirements to link to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services for § 441.313. Further, the burden associated with the requirements for managed care entities to report the data and information required under § 441.311 is estimated in the ICRs Regarding Compliance Reporting (§ 441.311(b)).

If a State opts to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services, the State would incur a burden. However, such burden would be less than the burden associated with posting the information required under § 441.311 on their own website. We are unable to estimate the number of States that may opt to comply with the requirements at § 441.313 by linking to the web pages of the managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, or primary care case management entity that are authorized to provide services. As a result, we do not take into account the option in our burden estimate and conservatively assume that all States subject to the requirements at § 441.313 by posting the information required under § 441.311 on their own website.

We estimate both a one-time and ongoing burden to implement these requirements at the State level.

a. One Time Website Transparency Requirements: States (§ 441.313)

The burden associated with the website transparency requirements proposed at § 441.313 will affect the 48 States (including Washington DC) that deliver HCBS under sections 1915(c), (i), (j), or (k) authorities. We estimate both a one-time and ongoing burden to implement these requirements at the State level. In developing our burden estimate, we assumed that States would provide the data and information that States are required to report under newly proposed § 441.311 through an existing website, rather than develop a new website to meet this requirement.

With regard to the one-time burden, based on the website transparency requirements, we estimate it would take: 24 hours at \$108.68/hr for an administrative services manager to determine the content of the website; 80 hours at \$92.92/hr for a computer programmer or contractor to develop the website; 3 hours at \$110.82/hr for a general and operations manager to review and approve the website; and 2 hours at \$204.82/hr for a chief executive to review and approve the website. In aggregate, we estimate a one-time burden of 5,232 hours (48 States x 109 hr) at a cost of \$517,633 (48 States x [(24 hr x \$108.68/hr) + (80 hr x \$92.92/hr) + (3 hr x \$110.82/hr) + (2 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$258,817 (\$517,633 x 0.50) per year.

TABLE 30: Summary of the One-Time Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No.	Total	Frequency	Time per	Total	Wage	Total Cost	State
	Respondents	Responses		Response (hr)	Time (hr)	(\$/hr)	(\$)	Share (\$)/year
Determine content of website	48	48	Once	24	1,152	108.68	125,199	62,600
Develop website	48	48	Once	80	3,840	92.92	356,813	178,406
Review and approve the website at the management level	48	48	Once	3	144	110.82	15,958	7,979
Review and approve the website at the executive level	48	48	Once	2	96	204.82	19,663	9,831
Total	48	192	Once	Varies	5,232	Varies	517,633	258,816

b. Ongoing Website Transparency Requirements: States (§ 441.313)

With regard to the State on-going burden related to the website transparency requirement, per quarter we estimate it would take: 8 hours at \$108.68/hr for an administrative services manager to provide updated data and information for posting and to verify the accuracy of the website; 20 hours at \$92.92/hr for a computer programmer or contractor to update the website; 3 hours at \$110.82/hr for a general and operations manager to review and approve the website; and 2 hours at \$204.82/hr for a chief executive to review and approve the website. In aggregate, we estimate an ongoing annual burden of 6,336 hours (33 hr x 48 States x 4 quarters) at a cost of \$666,228 (48 States x 4 quarters x [(8 hr x \$108.68/hr) + (20 hr x \$92.92/hr) + (3 hr x \$110.82/hr) + (2 hr x \$204.82/hr)]). Taking into account the Federal contribution to Medicaid administration, the estimated State share of this cost would be \$333,114 (\$666,228 x 0.50) per year.

TABLE 31: Summary of the Ongoing Burden for States for the Website Transparency Requirements at § 441.313

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Provide updated data and information for posting and verify the accuracy of the website	48	192	Quarterly	8	1,536	108.68	166,932	83,466
Update website	48	192	Quarterly	20	3,840	92.92	356,813	178,406
Review and approve website at the management level	48	192	Quarterly	3	576	110.82	63,832	31,916
Review and approve website at the executive level	48	192	Quarterly	2	384	204.82	78,651	39,325
Total	48	768	Quarterly	Varies	6,336	Varies	666,228	333,114

11. ICRs Regarding Payment Rate Transparency (§ 447.203)

The following proposed changes will be submitted to OMB for review under control number 0938–1134 (CMS–10391).

This proposed rule would update documentation requirements in § 447.203. To develop the burden estimates associated with these changes, we account for the removal of existing information collection requirements in current § 447.203(b), and the introduction of new requirements at proposed 447.203(b) and (c). As described later in this section, we estimate the impact of the proposed revisions to § 447.203 would result in a net burden reduction. We do not anticipate any additional information collection burden from the conforming edits proposed in § 447.204, as the conforming edits merely alter the items submitted as part of an existing submission requirement, and the burden of producing those items is reflected in the estimates related to § 447.203, including instances where we propose to move language from § 447.204 to § 447.203.

a. Removal of Access Monitoring Review Plan: States (§ 447.203(b)(1) through (8))

The burden reduction associated with the removal of § 447.203(b)(1) through (8) consists of the removal of time and effort necessary to develop and publish AMRPs, perform ongoing monitoring, and corrective action plans.

Current § 447.203(b)(1) and (2) describes the minimum factors that States must consider when developing an AMRP. Specifically, the AMRP must include: input from both Medicaid beneficiaries and Medicaid providers, an analysis of Medicaid payment data, and a description of the specific measures the State will use to analyze access to care. Current § 447.203(b)(3) requires that States include aggregate percentage comparisons of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates or Medicare rates) and private health coverage rates within geographic areas of the State. Current § 447.203(b)(4) describes the minimum content that must be included in the monitoring plan. States are required to describe: measures the State uses to analyze access to care issues, how the measures relate to the overarching framework, access issues that are discovered as a result of the review, and the State Medicaid agency's recommendations on the sufficiency of access to care based on the review. Current § 447.203(b)(5) describes the timeframe for States to develop the AMRP and complete the data review for the following categories of services: primary care, physician specialist services, behavioral health, pre- and post-natal obstetric services including labor and delivery, home health, any services for which the State has submitted a SPA to reduce or restructure provider payments which changes could result in diminished access, and additional services as determined necessary by the State or CMS based on complaints or as selected by the State. While the initial AMRPs have been completed, the plan must be updated at least every 3 years, but no later than October 1 of the update year. Current § 447.203(b)(6)(i) requires that any time a State submits a SPA to reduce provider payment rates or restructure provider payments in a way that could diminish access, the State must submit an AMRP associated with the services

affected by the payment rate reduction or payment restructuring that has been completed within the prior 12 months.

Section 447.203(b)(6)(ii) requires that States have procedures within the AMRP to monitor continued access after implementation of a SPA that reduces or restructures payment rates. The monitoring procedures must be in place for a period of at least 3 years following the effective date of the SPA. However, States were already required to submit information on compliance with section 1902(a)(30)(A) of the Act prior to the 2015 final rule with comment period. Therefore, removal of § 447.203(b)(6)(ii) will result in a burden reduction.

Finally, we note that this section references the proposed rescission of the current AMRP process contained in § 447.203(b)(1) to § 447.203(b)(8). However, the requirements of paragraph (b)(7) are reflected in proposed paragraph (b)(4), and the requirements of paragraph (b)(8) are reflected in proposed paragraph (c)(5). As such, there is not a change in impact related to the rescission of these specific aspects of the AMRP process, should our proposals be finalized, and are not reflected in this section.

In our currently approved information collection request, we estimated that the requirements to develop and make the AMRPs publicly available for the specific categories of Medicaid services will affect each of the 50 State Medicaid programs and the District of Columbia (51 total respondents). We will use that estimate here as well, although we note that the figure does not represent solely those States, but may include territories not exempt under waivers, and exclude States not subject due to reliance entirely on managed care (with no beneficiaries receiving any benefits through FFS delivery), and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this proposed rule. We further note that the one-time cost estimates have already been met for AMRPs, and the ongoing monitoring requirements are every 3 years. As such, the estimates in this section for burden reduction are for 17 respondents, one-third of the 51 affected respondents, to provide an annual estimate of the reduced burden.

We estimated that every 3 years, it would take: 80 hours at \$54.26/hr for a research analyst to gather data, 80 hours at \$100.80/hr for an information analyst to analyze the data, 100 hours at \$96.66/hr for a management analyst to develop the content of the AMRP, 40 hours at \$77.28/hr for a business operations specialist to publish the AMRP, and 10 hours at \$110.82/hr for managerial staff to review and approve the AMRP. In aggregate, and as shown in Table 35, we estimate the reduced annual burden of the rescission of the ongoing AMRP requirements would be minus 5,270 hours (17 States x 310 hr) and minus \$446,593 (17 States x [(80 hr x \$54.26/hr) + (80 hr x \$100.80/hr) + (100 hr x \$96.66/hr) + (40 hr x \$77.28/hr) + (10 hr x \$110.82/hr)]). Taking into account the 50 percent Federal contribution for administrative expenditures, the rescission represents a saving to States of minus \$223,297 (\$446,593 x 0.50).

The currently approved ongoing burden associated with the requirements under § 447.203(b)(6)(ii) is the time and effort it takes each of the State Medicaid programs to monitor continued access following the implementation of a SPA that reduces or restructures payment rates. In our currently approved information collection request, we estimate that in each SPA submission cycle, 22 States would submit SPAs to implement rate changes or restructure provider payments based on the number of submissions received in FY 2010. Using our currently approved burden estimates we estimate a reduction of: 40 hours at \$96.66/hr for a management analyst to develop the monitoring procedures, 24 hours at \$96.66/hr for a management analyst to periodically review the monitoring results, and 3 hours at \$110.82/hr for a general and operations manager to review and approve the monitoring procedures. In aggregate, we estimate burden reduction of minus 1,474 hours (22 Respondents x 67 hr) and minus \$143,411 (22 States x [(40 hr x \$96.66/hr) + (24 hr x \$96.66/hr) + (3 hr x \$110.82/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost reduction is adjusted to \$71,706 (\$143,411 x 0.50).

TABLE 32: Summary of Annual Burden Reduction Associated with Removal of Access Monitoring Review Plan Requirements (§ 447.203(b)(1) through (8))

Requirement	No. Respondent	Total Response s	Frequenc y	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
Rescission of §447.203(b)(1) through (b)(6)(i)	17	17	Triennial (figures are annualized	(310)	(5,270)	Varies	(446,593)	(223,297)
Rescission of § 447.203(b)(6)(i i)	22	22	Varies (figures are annualized	(67)	(1,474)	Varies	(143,411)	(71,706)
TOTAL	39	39	Varies	Varies	(6,744)	Varies	(590,004)	(295,003)

b. Payment Rate Transparency (§ 447.203(b)(1) through (5))

We are proposing to replace the AMRP requirements with a new payment rate transparency requirement at § 447.203(b)(1) through (5). The burden associated with the proposed payment rate transparency requirement consists of the time and effort to develop and publish a Medicaid FFS provider payment rate information and analysis.

Proposed § 447.203(b)(1) specifies that all FFS Medicaid payments must be published on a publicly accessible website that is maintained by the State. Proposed § 447.203(b)(2) specifies the service types that are subject to the proposed payment analysis, which include: primary care services; obstetrical and gynecological services; outpatient behavioral health services; and certain HCBS. Proposed § 447.203(b)(3) describes the required components of the payment analysis to include, for services in proposed § 447.203(b)(2)(i) through (iii), a percentage comparison of Medicaid payment rates to the most recently published Medicare payment rates effective for the time period for each of the service categories specified in paragraph (b)(2). We also specify that the payment analysis must include percentage comparisons made on the basis of Medicaid base payments. For HCBS described in proposed § 447.203(b)(2)(iv), we propose to require a State-based comparison of average hourly payment rates. Proposed § 447.203(b)(4) details the payment analysis timeframe, with the first payment analysis required to be published by the State agency by January 1, 2026, and updated every 2 years by January 1. Proposed

§ 447.203(b)(5) describes our mechanism for ensuring compliance and that we may take compliance action against a State that fails to meet the requirements of the payment rate transparency, comparative payment rate analysis, and payment rate disclosure provisions in preceding proposed paragraphs in § 447.203(b) including a deferral or disallowance of certain of the State's administrative expenditures following the procedures described at part 430, subpart C.

We estimate that the proposed requirements to complete and make publicly available all FFS Medicaid payments and the comparative payment rate analysis and payment rate disclosures under § 447.203(b)(1) through (5) for the specific categories of Medicaid services would affect 51 total respondents, based on the estimate in the prior section regarding the variation in States and territories subject to these requirements. We propose to require applicable States and territories to publish all FFS Medicaid payments initially by January 1, 2026, while future updates to the payment rate transparency information would depend on when a State submits a SPA updating provider payments and we have approved that SPA. As such, we assume 51 one-time respondents for the initial rates publication. Because the comparative payment rate analysis and payment rate disclosure requirement is biennial, we assume 26 annual respondents in any given year, and we will assume this figure would account for the updates made following a rate reduction SPA or rate restructuring SPA approval. The proposed comparative payment rate analysis would be similar to the current requirement at § 447.203(b)(3) that requires AMRPs to include a comparative payment rate analysis against public or private payers. The inclusion of levels of provider payment available from other payers is also one of five required components of the AMRP as specified by current § 447.203(b)(1). To estimate the burden associated with our proposed comparative payment rate analysis and payment rate disclosure provisions, we assume this work would require approximately 25 percent of the ongoing labor hour burden that we previously estimated to be required by the entire AMRP, to account for the service categories subject to the comparative payment rate analysis and payment rate disclosure in proposed

§ 447.203(b)(2) as decreased from the full body of AMRP service requirements. We invite comment on these estimated proportions.

With regard to the developing and publishing the payment rate transparency data at proposed § 447.203(b)(1), we estimate a low one-time and ongoing burden due to the data being available, and the main work required to meet the proposed requirement would be formatting and web publication. As such, we estimate it would initially take: 5 hours at \$54.26/hr for a research assistant to gather the data, 5 hours at \$77.28/hr for a business operations specialist to publish, and 1 hour at \$110.82/hr for a general and operations manager to review and approve the rate transparency data. In aggregate, we estimate a one-time burden of 561 hours (51 Respondents x 11 hr) at a cost of \$39,195 (51 Respondents x [(5 hr x \$54.26/hr) + (5 hr x \$77.28/hr) + (1 hr x \$110.82/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$19,597 (\$39,195 x 0.50).

For the ongoing cost to update assumed to take place every 2 years (although we are proposing that updates would only be required as necessary to keep the data current, with any update made no later than 1 month following the date of CMS approval of the SPA or similar amendment providing for the change), we estimate an annualized impact on 26 respondents (51 respondents every 2 years) of: 2 hours at \$54.26/hr for a research assistant to update the data, 1 hour at \$77.28/hr for a business operations specialist to publish the updates, and 1 hour at \$110.82/hr for a general and operations manager to review and approve the rate transparency update. In aggregate, we estimate an annualized burden of 104 hours (26 Respondents x 4 hr) at a cost of \$7,712 (26 Respondents x [(2 hr x \$54.26/hr) + (1 hr x \$77.28/hr) + (1 hr x \$110.82/hr)]). Taking into account the Federal administrative match of 50 percent, the requirement will cost States \$3,856 (\$7,712 x 0.50).

With regard to developing and publishing the comparative payment rate analysis and payment rate disclosure at proposed § 447.203(b)(2), we estimate it would take: 20 hours at \$54.26/hr for a research assistant to gather the data, 20 hours at \$100.80/hr for an information

analyst to analyze the data, 25 hours at \$96.66/hr for a management analyst to design the comparative payment rate analysis, 11 hours at \$77.28/hr for a business operations specialist to publish the comparative payment rate analysis and payment rate disclosure, and 3 hours at \$110.82/hr for a general and operations manager to review and approve the comparative payment rate analysis and payment rate disclosure. In aggregate, we estimate an annualized burden, based on 51 respondents every 2 years, of 2,054 (26 Respondents x 79 hr) at a cost of \$174,206 (26 States x [(20 hr x \$54.26/hr) + (20 hr x \$100.80/hr) + (25 hr x \$96.66/hr) + (11 hr x \$77.28/hr) + (3 hr x \$110.82/hr)]). We then adjust the total cost to \$87,103 (\$174,206 x 0.50) to account for the 50 percent Federal administrative match. We have summarized the total burdens in Table 33.

TABLE 33: Summary of Burden Associated with Proposed Payment Rate Transparency Requirements (Proposed § 447.203(b)(1) through (5))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(b)(1) Rate Transparency	51	51	One-time	11	561	Varies	39,195	19,597
§ 447.203(b)(1) Rate Transparency	26	26	Biannual (figures are annualized)	4	104	Varies	7,712	3,856
§ 447.203(b)(2) and (3) Rate Analysis	26	26	Biannual (figures are annualized)	79	2,054	Varies	174,206	87,103
TOTAL	51	103	Varies	Varies	2,719	Varies	221,113	110,557

c. Medicaid Payment Rate Interested Parties' Advisory Group (§ 447.203(b)(6))

The burden associated with the recordkeeping requirements proposed § 447.203(b)(6), specifically the online publication associated with the reporting and recommendations of the interested parties advisory group, would consist of the time and effort for all 50 States and the District of Columbia to:

- Appoint members to the interested parties' advisory group.
- Provide the group members with materials necessary to:
- ++ Review current and proposed rates.
- ++ Hold meetings.
- ++ Provide a written recommendation to the State.

 Publish the group's recommendations to a website maintained by the single State agency.

The proposed requirements would require varying levels of efforts for States depending on the existence of groups that may fulfil the requirements of this group. However, because it is unknown how many States would be able to leverage existing practices, and to what extent, this estimate does not account for those differences.

We estimate that it would take 40 hours at \$131.34/hr for a human resources manager to recruit interested parties and provide the necessary materials for the group to meet. In aggregate, we estimate a one-time burden of 2,040 hours (51 Respondents x 40 hr) at a cost of \$267,934 (2,040 hr x \$131.34/hr). Taking into account the 50 percent administrative match, the total one-time State cost is estimated to be \$133,967 (\$267,934 x 0.50).

We believe the ongoing work to maintain the needs of this group would take a human resources manager 5 hours at \$131.34/hr annually. Additionally, we estimate it would take 4 hours for the biennial requirement, or 2 hours annually at \$110.82/hr for an operations manager to review and prepare the recommendation for publication. In aggregate, we estimate an ongoing annualized burden of 182 hours (26 Respondents x 7 hr) at a cost of \$22,837 (26 Respondents x [(5 hr x \$131.34/hr) + (2 hr x \$110.82/hr)]). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to \$11,418 (\$22,837 x 0.50). We have summarized the total burdens in Table 34.

TABLE 34: Summary of Burden for Medicaid Payment Rate Interested Parties' Advisory Group

Requirement	No. Respondent s	Total Response s	Frequency	Time per Respons e (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(b)(6) (Establish advisory group)	51	51	One-time	40	2,040	131.3 4	267,93 4	133,96 7
§ 447.203(b)(6) (Support and publish recommendation	51	26	Biennial (figures are annualized	7	182	Varies	22,837	11,418
TOTAL	51	77	Varies	Varies	2,222	Varies	290,77 1	145,38 6

d. State Analysis Procedures for Payment Rate Reductions or Payment Restructuring
 (§ 447.203(c))

The proposed State analysis procedures for payment rate reductions and payment restructurings at § 447.203(c)(1) through (3) within this proposed rule effectively would replace payment rate reduction or payment restructuring procedures in current § 447.203(b)(6). As noted, the burden reduction associated with the removal of § 447.203(b)(6)(i) has already been accounted for in the recurring burden reduction estimate shown in Table 36 for the removal of the AMRP requirements, and the burden reduction associated with the removal of monitoring requirements at current § 447.203(b)(6)(ii) has been accounted for in Table 37. Our proposed replacement procedures at § 447.203(c)(1) through (3) would introduce new requirements as follows.

i. Initial State Analysis for Rate Reduction or Restructuring (§ 447.203(c)(1))

Proposed § 447.203(c)(1) would require that for States proposing to reduce or restructure provider payment rates, the State must document that their program and proposal meet all of the following requirements: (i) Medicaid rates in the aggregate for the service category following the proposed reduction(s) or restructurings are at or above 80 percent of most recent Medicare prices or rates for the same or a comparable set of services; (ii) Proposed reductions or restructurings result in no more than a 4 percent reduction of overall spending for each service category affected by a proposed reduction or restructuring in a single State fiscal year; and (iii)

Public process yields no significant access concerns or the State can reasonably respond to concerns.

Proposed § 447.203(c)(1) would apply to all States that submit a SPA that proposes to reduce or restructure provider payment rates. We limited our estimates for new information collection burden to the requirements at § 447.203(c)(1)(i) through (ii). Our estimates assume States will build off the comparative analysis required by proposed § 447.203(b)(2) through (4) to complete the requirements proposed by § 447.203(c)(1)(i), which will limit the additional information collection burden. We also assume no additional information collection burden posed by the public review process required by proposed § 447.203(c)(1)(iii), as this burden is encapsulated by current public process requirements at § 447.204.

The requirements of proposed § 447.203(c) apply to all 50 States and the District of Columbia, as well as US territories. We will again use the estimate of 50 utilized in preceding sections, which we note may include territories not exempt under waivers, and exclude States not subject due to reliance entirely on managed care (with no beneficiaries receiving any benefits through FFS delivery), and these figures fluctuate. As such, for consistency, we will maintain the estimate of 51 respondents subject to this proposed rule. While we cannot predict how many States will submit a rate reduction SPA or rate restructuring SPA in a given year, the figures from 2019 provide the best recent estimate, as the years during the COVID pandemic do not reflect typical behavior. In 2019, we approved rate reduction and rate restructuring SPAs from 17 unique State respondents. Therefore, to estimate the annualized number of respondents subject to this information collection burden, we will utilize a count of 17 respondents.

With regard to the burden associated with completing the required State analysis for proposed rate reductions or restructurings at § 447.203(c)(1), we estimate that it would take: 20 hours at \$96.66/hr for a management analyst to structure the rate reduction or restructuring analysis, 25 hours at \$100.80/hr for an information analyst to complete the rate reduction or restructuring analysis, and 3 hours at \$110.82/hr for a general and operations manager to review

and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 816 hours (17 States x 48 hr) at a cost of \$81,356 (17 States x [(20 hr x \$96.66/hr) + (25 hr x \$100.80/hr) + (3 hr x \$110.82/hr)]). Accounting for the 50 percent Federal administrative reimbursement, this adjusts to a total State cost of \$40,678 (\$81,356 x 0.50). We are soliciting public comment on these estimates as well as relevant State data to further refine the burden and time estimates.

TABLE 35: Burden Associated with Tier 1 State Analysis Procedures for Rate Reductions or Restructurings (Proposed § 447.203(c)(1))

Requ	irement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447	1.203(c)(1)	17	17	Annual	48	816	Varies	81,356	40,678
T	OTAL	17	17	Annual	48	816	Varies	81,356	40,678

ii. Additional State Rate Analysis (§ 447.203(c)(2))

Proposed § 447.203(c)(2) describes requirements for payment proposals that do not meet the requirements in paragraph (c)(1), requiring the State to provide the nature of the change and policy purpose, the rates compared to Medicare and/or other payers pre- and post-reduction or restructuring, counts/trends of actively participating providers by geographic areas, counts of FFS Medicaid beneficiaries residing in geographic areas/characteristics of the beneficiary population, service utilization trends, access to care complaints from beneficiaries, providers, and other interested parties, and the State's response to access to care complaints.

The information collection requirements proposed at § 447.203(c)(2) applies to those States that submit rate reduction or restructuring SPAs that do not meet one or more of the criteria proposed by § 447.203(c)(1). Using 2019 rate reduction and restructuring SPA figures, we estimate that 17 States will submit rate reduction or restructuring SPAs per year. Then, a 2019 Urban Institute analysis²⁶² indicates that 22 States (or 43 percent) have rates that meet the

²⁶² Zuckerman, S. et al. "Medicaid Physician Fees Remained Substantially Below Fees Paid By Medicare in 2019.", *Health Affairs*, Volume 40, Number 2, February 2021, p. 343-348, *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00611*, accessed August 31, 2022.

80 percent fee ratio threshold proposed in § 447.203(c)(1)(i) across all services. Although our proposal does not include all services, using this all services amount is our best method to estimate how many States may fall below on any given service without knowing which. Because we cannot predict the amount a State may propose to reduce, once or cumulatively for the SFY, and because failure of any one criterion in § 447.203(c)(1) would require additional analysis under § 447.203(c)(2), we will use that percentage to assess how many States would need to perform additional analysis. Using this percentage, we estimate that 7 (43 percent x 17) of the estimated 17 unique State respondents may submit rate reduction or restructuring SPAs meet that criteria for the streamlined analysis process under proposed § 447.203(c)(1). Therefore, we assume that 10 out of 17 unique annual State respondents who submit rate reduction or restructuring SPAs would also need to perform the additional analysis § 447.203(c)(2).

The required components of the review and analysis in proposed § 447.203(c)(2) are similar to the AMRP requirements found at current § 447.203(b)(1). However, due to the anticipated development and release of a template for States to facilitate completion of the required analysis, as well as the lack of a requirement to publish the analysis, we anticipate a moderately reduced burden associated with proposed § 447.203(c)(2) when compared to the burden estimated for the AMRPs.

With regard to our proposed requirements, we estimate that it would take: 64 hours at \$54.26/hr for a social science research assistant to gather data, 64 hours at \$100.80/hr for a computer and information analyst to analyze data, 80 hours at \$96.66/hr for a management analyst to structure the analyses and organize output, and 8 hours at \$110.82/hr for a general and operations manager to review and approve the rate reduction or restructuring analysis. In aggregate, we estimate a burden of 2,160 hours (10 States x 216 hr) at a cost of \$185,432 (10 States x [(64 hr x \$54.26/hr) + (64 hr x \$100.80/hr) + (80 hr x \$96.66/hr) + (8 hr x \$110.82/hr)]). The total cost is adjusted down to \$92,716 (\$185,432 x 0.50) for States after accounting for the

50 percent Federal administrative match. We are soliciting public comment on these estimates as well as relevant State data to further refine the burden and time estimates.

We do not assume any additional information collection imposed by the compliance procedures proposed by § 447.203(c)(3).

Table 41 shows our estimated combined annualized burden for § 447.203(c), which includes 17 States for § 447.203(c)(1) and 10 States for § 447.203(c)(2). In total, we estimate an annualized burden of 4,992 (1,104 hours + 2,160 hours) hours at a cost of \$443,848 (\$110,070 + \$74,172). This cost to States is then adjusted to \$221,924 after the 50 percent Federal administrative reimbursement is applied.

TABLE 36: Summary of Burden Associated with State Analysis Procedures for Rate Reductions or Restructurings (Proposed § 447.203(c))

Requirement	No. Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage (\$/hr)	Total Cost (\$)	State Share (\$)
§ 447.203(c)(1) (initial State analysis)	17	17	Annual	48	816	Varies	81,356	40,678
§ 447.203(c)(2) (additional State analysis)	12	12	Annual	216	2,160	Varies	185,432	92,716
TOTAL	17	29	Annual	264	2,976	Varies	266,788	133,394

D. Proposed Burden Estimate Summary

TABLE 37: Summary of Proposed Annual Burden Estimates

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number	Number of Respond ents	Numb er of Respo nses	Time per Respo nse (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Benefic iary Cost (\$)
§431.12 (Table 2) (MACs & BAGs)	OMB 0938- TBD (CMS- 10845)	51 States	153	Varie s	17,340	Varies	1,581,591	790,795	n/a
§441.301(c)(3) – One-time burden to States (Table 3) (Person- Centered Service Plans)	OMB 0938- TBD (CMS- 10854)	48 States	144	Varie s	528	Varies	62,203	31,102	n/a
§441.301(c)(3) – One-time burden to Managed Care Entities (Table 4) (Person-Centered Service Plans)	OMB 0938- TBD (CMS- 10854)	161 MCEs	322	Varie s	966	Varies	120,463	n/a	n/a
§441.301(c)(7) – One-time burden to States (Table 5) (Grievance Systems)	OMB 0938- TBD (CMS- 10854)	48 States	240	Varie s	24,960	Varies	2,481,926	1,240,964	n/a
§441.301(c)(7) – Ongoing burden to States (Table 6) (Grievance Systems)	OMB 0938- TBD (CMS- 10854)	48 States	58,55 8	Varie s	16,206	Varies	1,081,374	540,687	n/a
§441.302(a)(6) – One-time burden to States (Table 7) (Incident Management System)	OMB 0938- TBD (CMS- 10854)	48 States	384	Varie s	19,872	Varies	124,874,125	62,437,06	n/a
§441.302(a)(6) – Ongoing burden to States (Table 8) (Incident Management System)	OMB 0938- TBD (CMS- 10854)	48 States	283,6 38	Varie s	15,177	Varies	24,732,634	12,366,31	n/a
§441.302(a)(6) – Ongoing burden to Service Providers (Table 9) (Incident Management System)	OMB 0938- TBD (CMS- 10854)	15,742 provide rs	28,34	1	28,345	110.82	3,141,193	n/a	n/a
§441.302(a)(6) – One-time burden to Managed Care Entities (Table 10) (Incident Management System)	OMB 0938- TBD (CMS- 10854)	161 MCEs	805	Varie s	26,726	Varies	2,576,084	n/a	n/a
§441.302(a)(6) – Ongoing burden to Managed Care Entities (Table 11) (Incident Management System)	OMB 0938- TBD (CMS- 10854)	161 MCEs	7,286	Varie s	5,476	Varies	503,633	n/a	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number	Number of Respond ents	Numb er of Respo nses	Time per Respo nse (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Benefic iary Cost (\$)
§ 441.302(k) – One-time burden to States (Table 12) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	48 States	288	Varie s	9,792	Varies	916,693	458,347	n/a
§ 441.302(k) – Ongoing burden to States (Table 13) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	48 States	144	Varie s	432	Varies	47,231	23,616	n/a
§ 441.302(k) – One-time burden to service providers (Table 14) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	11,555 Provide	34,66 5	Varie s	959,06 5	Varies	81,897,911	n/a	n/a
§ 441.302(k) – Ongoing burden to service providers (Table 15) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	11,555 Provide	34,66	Varie s	242,65	Varies	21,553,542	n/a	n/a
§ 441.302(k) – One-time burden to managed care entities (Table 16) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	161 MCEs	644	Varie s	15,778	Varies	1,486,877	n/a	n/a
§ 441.302(k) – Ongoing burden to managed care entities (Table 17) (HCBS Payment Adequacy)	OMB 0938- TBD (CMS- 10854)	161 MCEs	322	Varie s	1,288	Varies	155,713	n/a	n/a
§441.303(f)(6), § 441.311(d)(1) – One-Time burden to States (Table 18) (Supporting Documentation for HCBS Access)	OMB 0938- TBD (CMS- 10854)	39 States	156	Varie s	1,599	Varies	169,236	84,618	n/a
§441.303(f)(6), § 441.311(d)(1) – Ongoing burden to States (Table 19) (Supporting Documentation for HCBS Access)	OMB 0938- TBD (CMS- 10854)	39 States	156	Varie s	585	Varies	67,639	33,820	n/a
§441.311(d)(2)(i) One-Time burden to States (Table 20) (Additional HCBS Access Reporting)	OMB 0938- TBD (CMS- 10854)	48 States	240	Varie s	6,000	Varies	591,154	295,577	n/a
§441.311(d)(2)(i) Ongoing burden to States (Table 21) (Additional HCBS Access Reporting)	OMB 0938- TBD (CMS- 10854)	48 States	240	Varie s	2,160	Varies	222,888	111,444	n/a
§441.311(d)(2)(i) One-Time burden to managed care entities (Table 22) (Additional HCBS Access Reporting)	OMB 0938- TBD (CMS- 10854)	161 MCEs	644	Varie s	9, 177	Varies	918,479	n/a	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number	Number of Respond ents	Numb er of Respo nses	Time per Respo nse (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Benefic iary Cost (\$)
§441.311(d)(2)(i) Ongoing burden to managed care entities (Table 23) (Additional HCBS Access Reporting)	OMB 0938- TBD (CMS- 10854)	161 MCEs	644	Varie s	5,474	Varies	558,303	n/a	n/a
§441.311(b)(1) Ongoing burden to States (Table 24) (Incident Management System Assessment) ^a	OMB 0938- 1362 (CMS- 10692)	48 States	96	Varie s	96	Varies	7,976	3,988	n/a
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 25)	OMB 0938- 0272 (CMS- 372(S))	48 States	253	(44)	(11,13 2)	75.32	(860,281)	(430,140)	n/a
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)-(4) (Table 26)	OMB 0938- TBD (CMS- 10854)	48 States	144	Varie s	2,640	Varies	221,093	110,546	n/a
§441.311(c) One-time burden to States (Table 27) (HCBS Quality Measure Set)	OMB 0938- TBD (CMS- 10854)	48 States	288	Varie s	64,560	Varies	5,141,918	2,570,959	n/a
§441.311(c) Ongoing burden to States (Table 28) (HCBS Quality Measure Set) ^b	OMB 0938- TBD (CMS- 10854)	24 States	288	Varie s	117,84 0	Varies	4,087,183	2,043,592	n/a
§441.311(c) Ongoing burden to beneficiaries (Table 29) (HCBS Quality Measure Set)	OMB 0938- TBD (CMS- 10854)	48,000 benefici aries	24,00	0.75	18,000	20.71	n/a	n/a	372,78 0
§441.313 One-time burden to States (Table 30) (Website Transparency)	OMB 0938- TBD (CMS- 10854)	48 States	192	Varie s	5,232	Varies	517,633	258,816	n/a
§441.313 Ongoing burden to States (Table 31) (Website Transparency) ^d	OMB 0938- TBD (CMS- 10854)	48 States	768	Varie s	6,336	Varies	666,228	333,114	n/a
Removal of § 447.203(b)(1)-(6)(i)) (Table 32) (Removal of AMRP)	OMB 0938– 1134 (CMS– 10391)	51 States and Territor ies	17	(310)	(5,270)	varies	(446,593)	(223,297)	n/a
Removal of § 447.203(b)(6)(ii) (Table 32) (Removal of AMRP)	OMB 0938– 1134 (CMS– 10391)	51 States and Territor ies	22	(67)	(1,474)	varies	(143,411)	(71,706)	n/a

Regulation Section(s) in Title 42 of the CFR	OMB Control Number (CMS ID Number	Number of Respond ents	Numb er of Respo nses	Time per Respo nse (hr)	Total Time (hr)	Hourly Labor Rate (\$/hr)	Total Labor Cost (\$)	State Share (\$)	Total Benefic iary Cost (\$)
§ 447.203(b)(1) (Table 33) (Rate transparency)	OMB 0938- 1134 (CMS- 10391)	51 States and Territor ies	26	4	104	varies	7,712	3,856	n/a
§ 447.203(b)(2) (Table 33) (Rate analysis)	OMB 0938- 1134 (CMS- 10391)	51 States and Territor ies	26	79	2,054	varies	174,206	87,103	n/a
§ 447.203(b)(6) (Table 34) (advisory group)	OMB 0938- 1134 (CMS- 10391)	51 States and Territor ies	26	7	182	varies	22,837	11,418	n/a
§ 447.203(c)(1) (Table 35) (initial State analysis)	OMB 0938- 1134 (CMS- 10391)	51 States and Territor ies	17	48	816	varies	81,356	40,678	n/a
§ 447.203(c)(2) (Table 36) (additional State analysis)	OMB 0938- 1134 (CMS- 10391)	51 States and Territor ies	12	216	2,160	varies	185,432	92,716	n/a
TOTAL		Varies	478,85 8	Varies	1,600,1 22	Varies	279,404,181	82,205,31	504,18

a/ The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per State reflected in Table 24.

E. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at www.cms.hhs.gov/PaperworkReductionActof1995, or call the Reports Clearance Office at 410–786–1326.

b/ The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per State reflected in Table 32.

c/ The reporting requirement is every other year. Therefore, the on-going burden reflected in this table is half of the on-going burden per discussed above.

d/ The reporting requirement is quarterly. Therefore, the on-going burden reflected in this table is four times the on-going burden discussed above.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the DATES and ADDRESSES section of this proposed rule and identify the rule (CMS-2442-P), the ICR's CFR citation, and OMB control number.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

- A. Statement of Need
- 1. Medicaid Advisory Committee

The changes to § 431.12 are intended to provide beneficiaries a greater voice in State Medicaid programs. In making policy and program decisions, it is vital for States to incorporate the perspective and experience of those served by the Medicaid program. States are currently required to operate a MCAC, made up of health professionals, consumers, and State representatives to "advise the Medicaid agency about health and medical care services." This rule establishes new requirements for a MAC in place of the MCAC, with additional membership requirements to include a broader group of interested parties, to advise the State Medicaid agency on matters related to the effective administration of the Medicaid program. We seek to expand the viewpoints represented on the MAC, to provider States with richer feedback on Medicaid program and policy issues. States are already required to set up and use MCACs. The proposed changes will result in the State also setting up a smaller group, the BAG which will likely have a cost implication. The additional cost will depend on whether or not States already have a beneficiary committee – we know that many States already do. This smaller

group which feeds into the larger MCAC will benefit the Medicaid program by creating a forum for beneficiaries to weigh in on key topics and share their unique views as Medicaid program participants. The new provisions of § 431.12 also enhance transparency and accountability through public reporting requirements related to the operation and activities of the MAC and BAG, and guidelines for operation of both bodies.

2. Home and Community-Based Services (HCBS)

The proposed changes at part 441, subpart G, seek to amend and add new Federal requirements, which are intended to improve access to care, quality of care, and health outcomes, and strengthen necessary safeguards that are in place to ensure health and welfare, and promote health equity for people receiving Medicaid-covered HCBS. The provisions in this proposed rule are intended to achieve a more consistent and coordinated approach to the administration of policies and procedures across Medicaid HCBS programs in accordance with section 2402(a) of the Affordable Care Act, and is made applicable to part 441, subparts J, K, and M, as well as part 438 to achieve these goals.

Specifically, the proposed rule seeks to: strengthen person-centered services planning and incident management systems in HCBS; require minimum percentages of Medicaid payments for certain HCBS to be spent on compensation for the direct care workforce; require States to establish grievance systems in FFS HCBS programs; report on waiver waiting lists in section 1915(c) waiver programs, service delivery timeframes for certain HCBS, and a standardized set of HCBS quality measures; and promote public transparency related to the administration of Medicaid-covered HCBS through public reporting on measures related to incident management systems, critical incidents, person-centered planning, quality, access, and payment adequacy.

In 2014, we released guidance²⁶³ for section 1915(c) waiver programs, which described a process in which States were to report on State-developed performance measures to demonstrate

²⁶³ https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/3-cmcs-quality-memo-narrative 0 71.pdf.

that they meet the six assurances that are required for section 1915(c) waiver programs. Those six assurances include the following:

- 1. Level of Care: The State demonstrates that it implements the processes and instrument(s) specified in its approved waiver for evaluating/reevaluating an applicant's/waiver participant's level of care consistent with care provided in a hospital, nursing facility, or Intermediate Care Facilities for Individuals with Intellectual Disabilities.
- 2. Service Plan: The State demonstrates it has designed and implemented an effective system for reviewing the adequacy of service plans for waiver participants.
- 3. Qualified Providers: The State demonstrates that it has designed and implemented an adequate system for assuring that all waiver services are provided by qualified providers.
- 4. Health and Welfare: The State demonstrates it has designed and implemented an effective system for assuring waiver participant health and welfare.
- 5. Financial Accountability: The State demonstrates that it has designed and implemented an adequate system for insuring financial accountability of the waiver program.
- 6. Administrative Authority: The Medicaid Agency retains ultimate administrative authority and responsibility for the operation of the waiver program by exercising oversight of the performance of waiver functions by other State and local/regional non-State agencies (if appropriate) and contracted entities.

Despite these assurances, there is evidence that State HCBS systems still need to be strengthened and that there are gaps in existing reporting requirements. We believe that this proposed rule is necessary to address these concerns and strengthen HCBS systems. The requirements in this proposed rule are intended to supersede and fully replace the reporting and performance expectations described in the 2014 guidance for section 1915(c) waiver programs. They are also intended to promote consistency and alignment across HCBS programs, as well as delivery systems, by applying the requirements (where applicable) to sections 1915(i), (j), and (k) authorities State plan benefits and to both FFS and managed care delivery systems.

3. Fee-for-Service (FFS)

Provisions under § 447.203 from this proposed rule would impact States' required documentation of compliance with section 1902(a)(30)(A) of the Act to "assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area." We have received comments from State agencies that the existing AMRP requirement first established by the 2015 final rule with comment period imposes excessive administrative burden for its corresponding value in demonstrating compliance with section 1902(a)(30)(A) of the Act.

This proposed rule would replace the existing AMRP requirement with a more limited payment rate transparency requirement under proposed § 447.203(b), while requiring a more detailed access impact analysis (as described at proposed § 447.203(c)(2)) when a State proposes provider rate reductions or restructurings that exceed certain thresholds for a streamlined analysis process under proposed § 447.203(c)(1). By limiting the data collection and publication requirements imposed on all States, while targeting certain provider rate reductions or restructuring proposals for a more detailed analysis, this proposed rule would provide administrative burden relief to States while maintaining a transparent and data-driven process to assure State compliance with section 1902(a)(30)(A) of the Act.

B. Overall Impact

We have examined the impacts of this rule as required by EO 12866 on Regulatory Planning and Review (September 30, 1993), EO 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), EO 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2))

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of

available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 as amended by Executive Order 14094 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules. Accordingly, this proposed rule is not a "significant" rule under section 3(f)(1) of the Executive Order, as the aggregate amount of benefits and costs will not meet the \$200 million threshold in any 1 year.

Based on our estimates using a "no action" baseline in accordance with OMB Circular A-4, (available at

https://www.whitehouse.gov/wpcontent/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf),
OMB's Office of Information and Regulatory Affairs has determined that this rulemaking is
"significant" according to section 3(f)(4), raising legal or policy issues for which centralized
review would meaningfully further the President's priorities, or the principles set forth in
Executive Order 12866. Therefore, OMB has reviewed these proposed regulations, and the
Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

As mentioned in the prior section, and in accordance with OMB Circular A-4, the following estimates were determined using a "no action" baseline. That is, our analytical

baseline for impact is a direct comparison between the proposed provisions and not proposing them at all.

- 1. Benefits
- a. Medicaid Advisory Committees (MAC)

We believe the changes to § 431.12 would benefit State Medicaid programs and those they serve by ensuring that beneficiaries have a significant role in advising States on the experience of receiving health care and services through Medicaid. These benefits cannot be quantified. However, the BAG and a more diverse and transparent MAC will provide opportunities for richer interested parties feedback and expertise to positively impact State decision making on Medicaid program and policy chances. For example, beneficiary feedback on accessing health care services and the quality of those services can inform decisions on provider networks and networks adequacy requirements. Issues that States need to address, like cultural competency of providers, language accessibility, health equity, and disparities and biases in the Medicaid program, can be revealed through beneficiary experiences. The MAC falls into the Public Administration 921 Executive, Legislative, and Other General Government Support.

b. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

The proposed changes benefit Medicaid beneficiaries and States by requiring States to demonstrate through reporting requirements that they provide safeguards to assure eligibility for Medicaid-covered care and services is determined and provided in a manner that is in the Medicaid beneficiaries' best interest, although these potential benefits cannot be monetarily quantified at this time. The proposed changes would provide further safeguards that ensure health and welfare by strengthening the person-centered service plan requirements, establishing grievance systems, amending requirements for incident management systems, and establishing new reporting requirements for States, and contracted managed care entities identified by the North American Industry Classification System (NAICS) industry code (Direct Health and Medical Insurance Carriers (524114).

These changes would benefit individuals on HCBS waiver wait lists, and individuals who receive homemaker, home health aide, and personal care services, under the amended and proposed regulations found at §§ 441.301(c), 441.302(a)(6), 441.302(h), 441.303(f), 441.311, and cross-referenced in §§ 441.464, 441.555(b)(2)(iv), 441.570, and 441.745(a)(1)(iii). These potential benefits cannot be monetarily quantified at this time.

c. Home and Community-Based Services (HCBS) Payment Adequacy

The proposed rule adds new requirements at §§ 441.302(k) and 441.311 (cross-referenced at §§ 441.464(f) and 441.745(a)(1)(vi)) that require States to demonstrate through reporting that payments to providers are sufficient to provide access to care that is at least comparable to that of the general population in the same geographic location, in accordance with section 1902(a)(30(A) of the Act. This proposed rule seeks to address access to care that is being affected by direct care workforce shortages.

Through this proposed rule, which establishes certain minimum thresholds for compensation for direct care workers, we can better ensure payment adequacy to a provider population experiencing worker shortages that impact beneficiary access. States will be required to report annually to us on the percent of payments for certain HCBS that are spent on compensation for direct care workers and will be required to separately report on payments for services that are self-directed. States may benefit from reporting in the aggregate for each service subject to the requirement across HCBS programs and delivery systems, which minimizes administrative burden while providing us better oversight of compensation of the direct care workforce, although these potential benefits cannot be monetarily quantified at this time due to the variety of State data collection approaches.

d. Home and Community-Based Services (HCBS) Quality Measure Set Reporting

As described in section II.B.8. of this proposed rule, on July 21, 2022, we issued State Medicaid Director Letter (SMDL) # $22-003^{264}$ to release the first official version of the HCBS

²⁶⁴ https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf.

Quality Measure Set. This proposed rule provides definitions and sets forth requirements proposed at § 441.312 that expand on the HCBS Quality Measure Set described in the SMDL. By expanding and codifying aspects of the SMDL, we can better drive improvement in quality of care and health outcomes for beneficiaries receiving HCBS. States will also benefit from the clarity afforded by this proposed rule, and from the assurance that other States they may be looking to for comparison are adhering to the same requirements. The clarity and assurance, at this time, cannot be measured.

e. Fee-for-Service (FFS) Payment Transparency

The proposed changes to § 447.203 would update requirements placed on States to document access to care and service payment rates. The proposed updates create a systematic framework through which we can ensure compliance with section 1902(a)(30)(A) of the Act, while reducing existing burden on States and maximizing the value of their efforts, as described in section III.C.11.a of this rule.

The proposed payment rate transparency provisions at § 447.203(b) create a process that would facilitate transparent oversight by us and other interested parties. By requiring States to calculate Medicaid payment rates as a percent of corresponding Medicare payment rates, this provision offers a uniform benchmark through which us and interested parties can assess payment rate sufficiency. When compared to the existing AMRP requirement, the rate analysis proposed by § 447.203(b) should improve the utility of the reporting, while reducing the associated administrative burden, as reflected in the Burden Estimate Summary Table 37. Proposed updates at § 447.203(c) specify required documentation and analysis when States propose to reduce or restructure provider payment rates. By establishing thresholds at § 447.203(c)(1), this proposed rule would generally limit the more extensive access review prescribed by § 447.203(c)(2) to those SPAs that we believe more likely to cause access concerns. In doing so, these proposed updates reduce the State administrative burden imposed by existing documentation requirements for proposed rate reductions or restructurings, without

impeding our ability to ensure proposed rate reduction and restructuring SPAs comply with section 1902(a)(30)(A) of the Act. These burden reductions are reflected in the Collection of Information section of this rule.

When considering the benefits of these regulatory updates, we considered the possibility that the improved transparency required by § 447.203(b) could create upward pressure on provider payment rates, and that the tiered nature of documentation requirements set by § 447.203(c) could create an incentive for States to moderate proposed payment reductions or restructurings that were near the proposed thresholds that would trigger additional analysis and documentation requirements. If either of these rate impacts were to occur, existing literature implies there could be follow-on benefits to Medicaid beneficiaries, including but not limited to increased physician acceptance rates, ²⁶⁵ increased appointment availability, ²⁶⁶ and even improved self-reported health.²⁶⁷ However, nothing in this proposed rulemaking would require States to directly adjust payment rates, and we recognize that multiple factors influence State rate-setting proposals, including State budgetary pressures, legislative priorities, and other forces. These competing influences create substantial uncertainty about the specific impact of the proposed provisions at § 447.203 on provider payment rate-setting and beneficiary access. Rather, the specific intent and anticipated outcome of these provisions is the creation of a more uniform, transparent, and less burdensome process through which States can conduct required payment rate and access analyses and we can perform our oversight role related to provider payment rate sufficiency.

- 2. Costs
- a. Medicaid Advisory Committee (MAC)

States will incur additional costs (estimated below) in appointing and recruiting members

²⁶⁵ Holgash, K. and Martha Heberlein, *Health Affairs*, April 10, 2019.

²⁶⁶ Candon, M., et al. JAMA Internal Medicine, January 2018, p. 145-146.

²⁶⁷ Alexander, D., and Molly Schnell. "The Impacts of Physician Payments on Patient Access, Use, and Health", National Bureau of Economic Research, Working Paper 26095, July 2019 (revised August 2020), p. 1-74. https://www.nber.org/papers/w26095. Accessed June 16, 2022.

to the MAC and BAG and also developing and publishing bylaws, membership lists, and meeting minutes for the MAC and BAG. All of these costs can be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support) since States are the only entity accounted for in the MAC and BAG. How often these costs occur will vary in how often the State chooses to make changes such as add or replace members of the MAC and BAC or change its bylaws. Additionally, there will be new costs, estimated below, for States related to meeting logistics and administration for the BAG. All of these new costs can also be categorized under the NAICS Code 921 (Executive, Legislative, and Other General Government Support). Since most States are already holding MAC meetings under current regulatory requirements, any new costs related to MAC requirements would likely be minimal. In terms of the BAG meeting costs, we estimate a total annual cost of \$532,627 for States. We estimate it will take a business operations specialist 10 hours to plan and execute each BAG meeting, at a total cost of \$155,448 (\$76.20/hour x 10 hours x 4 meetings/year) x 51 States and the District of Columbia). To satisfy the requirements of § 431.12(i)(4)(i), a public relations specialist will spend an estimated 80 hours/year supporting Medicaid beneficiary MAC and BAG members at a total cost of \$287,395 (\$70.44/hour x 80 hours) x 51 States and the District of Columbia). A chief executive in State government, as required by § 431.12(i)(4)(iii), will spend a total of 8 hours a year attending BAG meetings, which we estimate will be 2 hours in duration, 4 times a year at a total cost of \$48,984 (\$120.06/hour x 2 hours/meeting x 4 meetings) x 51 States and the District of Columbia). Each meeting of the BAG will cost States an estimated \$200 in meeting costs and telecommunication, at an annual total cost of \$40,800 (\$200 x 4 meetings) x 51 States and the District of Columbia).

There will also be a per meeting cost to States for financial support for beneficiary members participating in MAC and BAG meetings, as described in § 431.12(i)(4)(ii). We estimate a cost of \$75/beneficiary/meeting in the form of transportation vouchers, childcare reimbursement, meals, and/or other financial compensation. Assuming 4 meetings per year (with BAG and MAC meetings co-located and occurring on the same day) and an average of 8

beneficiary members on the BAG and MAC, the cost of financial support for beneficiary members across States is estimated to cost approximately \$122,400 annually ((\$75/beneficiary x 8 beneficiaries x 4 meetings/year) x 51 States and the District of Columbia). This cost will vary depending on the decisions States make around financial support, the number of beneficiary members of the BAG and MAC, and the number of meetings per year. We seek comment on the costs associated with planning, execution, and participation in the MAC and BAG meetings.

TABLE 38: Projected 5-Year Costs for Proposed Updates

		Cale	endar year (CY)		Total CY 2024-
Provision	2024 (\$ in millions)	2025 (\$ in millions)	2026 (\$ in millions)	2027 (\$ in millions)	2028 (\$ in millions)	2028 (\$ in millions)
§ 431.12 MAC & BAG logistic and admin support	0.533	0.532	0.532	0.532	0.532	2.663
§ 431.12 Financial support to MAC/BAG beneficiary members (cost will range per State)	0.122	0.122	0.122	0.122	0.122	0.612
Total	0.655	0.655	0.655	0.655	0.655	3.275

Costs will vary depending by State depending on how many in person meetings are held and how many Medicaid beneficiaries are selected for the MAC and BAG

b. Home and Community-Based Services (HCBS)

Costs displayed in Table 38 are inclusive of both one-time and ongoing costs. One-time costs are split evenly over the years leading up to the proposed effective date. For example, if a proposed provision takes effect 3 years after the final rule's publication, the one-time costs would be split evenly across each of the years leading to that effective date. Because costs are projected over 5 years, the total estimated costs exceed the amounts shown in the COI section. The estimates below do not account for higher costs associated with medical care, as the costs are related exclusively to reporting costs. Costs to States, the Federal government, and managed care entities do not account for enrollment fluctuations, as they assume a stable number of States operating HCBS programs and managed care entities delivering services through these programs.

Similarly, costs to providers and beneficiaries do not account for enrollment fluctuations. In the COI section, costs are based on a projected range of HCBS providers and beneficiaries. Given this uncertainty, here, we based cost estimates on the mid-point of the respective ranges and kept those assumptions consistent over the course of the 5-year projection. Per OMB guidelines, the projected estimates for future years do not consider ordinary inflation.

Table 39 summarizes the estimated ongoing costs for States, managed care entities (Direct Health and Medical Insurance Carriers (NAICS 524114)), and providers (Services for the Elderly and Persons with Disabilities (NAICS 624120) and Home Health Care Services (NAICS 621610)) from the COI section of the HCBS provisions of the proposed rule projected over 5 years. This comprises the entirety of anticipated quantifiable costs associated with proposed changes to part 441, subpart G. It is also possible that increasing the threshold from 86 percent to 90 percent for compliance reporting at § 441.311(b)(2) through (3) may lead to additional costs to remediate issues pertaining to critical incidents or person-centered planning. However, the various avenues through which States could address these concerns creates substantial uncertainty as to what those costs may be. While we acknowledge the potential for increased costs in a limited number of States that may fall within the gap between the existing and the proposed compliance thresholds, we do not quantify them here.

TABLE 39: Projected 5-Year Costs for Proposed Updates to 441 Subparts G, J, K, and M

		Cal	endar year (CY)		Total CY
	2024 (\$	2025 (\$	2026 (\$	2027 (\$	2028 (\$	2024-2028
	in	in	in	in	in	(\$ in
Provision	millions)	millions)	millions)	millions)	millions)	millions)
Proposed § 441.301(c)(3) (Person-						
Centered Service Plans)	0.06	0.06	0.06	-	-	0.18
Proposed § 441.301(c)(7)						
(Grievance Systems)	1.24	1.24	0.87	0.87	0.87	5.10
Proposed § 441.302(a)(6) (Incident						
Management System)	41.15	41.15	41.15	6.78	6.78	137.01
Proposed § 441.302(k) (HCBS						
Payment Adequacy)	21.08	21.08	21.08	21.08	21.73	106.03
Proposed §441.303(f)(6), §						
441.311(d)(1) (Supporting						
Documentation for HCBS Access)	0.06	0.06	0.06	0.07	0.07	0.30
Proposed §441.311(d)(2)(i)						
(Additional HCBS Access						
Reporting)	0.50	0.50	0.50	0.78	0.78	3.07
Proposed § 441.311(b)(1)(Incident						
Management System Assessment)	-	-	_	0.00	0.00	0.01
Removal of Current Form 372(S)						
Ongoing Reporting Information						
Collection	-	-		(0.84)	(0.84)	(1.68)
Proposed Form 372(S) Reporting						
Requirement to include Proposed §						
441.311(b)(2)-(4)	-	-	-	0.22	0.22	0.44
Proposed §441.311(c) (HCBS						
Quality Measure Set)	1.72	1.72	1.72	4.59	4.59	14.34
Proposed §441.313 (Website						
Transparency)	-	-	_	1.18	1.18	2.37
Total	65.80	65.80	65.44	34.74	35.39	267.18

The costs displayed in Table 40 are inclusive of costs anticipated to be incurred by State Medicaid agencies, the Federal government, providers, managed care entities, and beneficiaries. Table 40 distributes those costs across these respective entities.

TABLE 40: Projected Distribution of Costs for Proposed Updates to 42 CFR 441 Subpart G, J, K, and M

Costs associated with		Calendar year (CY)							
updates to § 42 CFR 441 Subparts G, J, K, and M	2024 (\$ in millions)	2025 (\$ in millions)	2026 (\$ in millions)	2027 (\$ in millions)	2028 (\$ in millions)	(\$ in millions)			
Total Costs associated with updates to 42 CFR 441									
subparts G, J, K, and M	65.80	65.80	65.44	34.74	35.39	267.18			
State Costs	21.88	21.88	21.69	4.59	4.50	74.54			
Federal Costs	21.88	21.88	21.69	4.59	4.50	74.54			
HCBS Provider Costs									
(Services for the Elderly and									
Persons with Disabilities									
(NAICS 624120) and Home									
Health Care Services (NAICS	• • • •	• • • •	• • • • •		24.50	400			
621610))	20.47	20.47	20.47	23.62	24.69	109.73			
Managed Care Entity Costs									
(Direct Health and Medical									
Insurance Carriers (NAICS									
524114))	1.58	1.58	1.58	1.43	1.19	7.35			

c. Fee-for-Service (FFS) Payment Rate Transparency

The costs associated with the payment rate transparency proposals are wholly associated with information collection requirements, and as such those impacts are reflected in the COI section of this rule. For ease of reference, and for projection purposes, we are including those costs here in Table 41.

TABLE 41: Projected 5-Year Costs for Proposed Updates to 42 CFR 447.203

		Calendar year (CY)							
	2024 (\$ in	2025 (\$ in	2026 (\$ in	2027 (\$ in	2028 (\$ in	2024-2028 (\$			
Provision	millions)	millions)	millions)	millions)	millions)	in millions)			
Removal of current § 447.203 (AMRPs)	-0.601	-0.601	-0.601	-0.601	-0.601	-3			
Proposed § 447.203(b)	0.516	0.209	0.209	0.209	0.209	1.353			
Proposed § 447.203(c)(SPAs)	0.276	0.276	0.276	0.276	0.276	1.38			
Total	0.191	-0.116	-0.116	-0.116	-0.116	-0.267			

TABLE 42: NAICS Classification of Services and Their Distribution of Costs

Services	NAICS	Percentage of Costs
Managed Care Entities	Direct Health and Medical Insurance Carriers (524114)	100 Percent
Home and Community-Based Services (HCBS)	Elderly and Persons with Disabilities (624120)	67 Percent
Home and Community-Based Services (HCBS)	Home Health Care Services (621610)	37 Percent

TABLE 43: One Time and Annual Costs Detailed

	Costs to States (\$)	Costs to Beneficiaries (\$)	Cost to Providers (\$)	Cost to Managed Care Entities (\$)	One Time Burden Overall Total (\$)	Annual Burden Overall Total (\$)
Regulatory Review	19,587.06	39,174.12		61,833.66	120,594.84	0
§ 431.12 Medical Care Advisory Committee Requirements	790,795	-	-	-	-	790,795
§441.301(c)(3) (Person- Centered Service Plans) (Table 3,4)	31,102	-	-	120,463	151,565	-
§441.301(c)(7) (Grievance Systems) (Table 5)	1,240,964	-	-	-	1,240,964	-
§441.301(c)(7) (Grievance Systems) (Table 6)	540,687	-	-	-	-	540,687
§441.302(a)(6) (Incident Management System) (Table 7,10)	62,437,000	-	-	2,576,084	65,009,084	-
§441.302(a)(6) (Incident Management System) (Table 8, 9, 10, 11)	12,366,317	-	3,141,193	503,633	-	16,011,132
§ 441.302(k) (HCBS Payment Adequacy) (Table 12,14, 16)	458,347	-	103,451,453	1,486,877	105,396,677	-
§ 441.302(k) (HCBS Payment Adequacy) (Table 13,15, 17)	23,616	-	21,553,542	155,713	-	21,732,871
§441.303(f)(6), § 441.311(d)(1) Supporting Documentation for HCBS Access (Table 18)	84,618	-	-	-	84,618	-
§441.303(f)(6), § 441.311(d)(1) Supporting Documentation for HCBS Access (Table 19)	33,820	-	-	-	-	33,820
§441.311(d)(2)(i) (HCBS Access Reporting) (Table 20, 22)	295,577	-	-	918,479	1,214,056	-
§441.311(d)(2)(i) (HCBS Access Reporting) (Table 21, 23)	111,444	-	-	558,303	-	669,747
§441.311(b)(1) (Incident Management System Assessment) (Table 24)	3,988	-	-	-	-	3,988
Removal of Current Form 372(S) Ongoing Reporting Information Collection (Table 25)	(\$430,140))	-	-	-	-	(\$430,140)

	Costs to States (\$)	Costs to Beneficiaries (\$)	Cost to Providers (\$)	Cost to Managed Care Entities (\$)	One Time Burden Overall Total (\$)	Annual Burden Overall Total (\$)
Form 372(S) Reporting Requirement to include Proposed § 441.311(b)(2)-(4) (Table 26)	110,546	-	-	-	-	110,546
441.311(c) (Table 27) (HCBS Quality Measure Set)	2,570,959	-	-	-	2,570,959	-
441.311(c) (Table 28,29) (HCBS Quality Measure Set)	2,043,592	504,180	-	-	-	2,547,772
§441.313 (Table 30) (Website Transparency)	258,816	-	-	-	258,816	-
§441.313 (Table 31) (Website Transparency)	333,114	-	-	-	-	333,114
§ 447.203(b)(1) (Table 33) (Rate transparency)	23,453	-	-	-	39,195	7,712
§ 447.203(b)(2) (Table 33) (Rate analysis)	87,103	-	-	-	-	174,206
§ 447.203(b)(6) (Table 34) (advisory group)	145,386	-	-	-	267,934	22,837
§ 447.203(c)(1) (Table 35) (initial State analysis)	40,678	-	-	-	-	81,356
§ 447.203(c)(2) (Table 36) (additional State analysis)	92,716	-	-	-	-	185,432

3. Transfers

Transfers are payments between persons or groups that do not affect the total resources available to society. They are a benefit to recipients and a cost to payers, with zero net effects. Because this rule proposes changes to requirements to State agencies without changes to payments from Federal to State governments, the transfer impact is null, and cost impacts are reflected in the other sections of this rule.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. There is uncertainty involved with accurately quantifying the number of

entities that will review the rule. However, for the purposes of this proposed rule we assume that on average, each of the 51 affected State Medicaid agencies will have one contractor per State review this proposed rule. This average assumes that some State Medicaid agencies may use the same contractor, others may use multiple contractors to address the various provisions within this proposed rule, and some State Medicaid agencies may perform the review in-house. We also assume that each affected managed care entity (estimated in the COI section to be 161 managed care entities) will review the proposed rule. Lastly, we assume that an average of two advocacy or interest group representatives from each State will review this proposed rule. In total, we are estimating that 314 entities (51 State Contractors + 161 Managed Care Entities + 102 Advocacy and Interest Groups) will review this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics, https://www.bls.gov/oes/current/oes_nat.htm, we consider medical and health service managers (Code 11-9111), as including the 51 State Contractors, 161 Managed Care Entities and 102 Advocacy and Interest Groups identified in the proposed rule, and we estimate that the cost of reviewing this rule is \$115.22 per hour, including fringe benefits and other indirect costs.

Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 3.33 hours for each individual to review half of this proposed rule ([100,000 words x 0.5] / 250 words per minute / 60 minutes per hour). For each entity that reviews the rule, the estimated cost is \$384.06 (3.33 hours x \$115.22). Therefore, we estimate that the total one-time cost of reviewing this regulation is \$120,594.84 (\$384.06 per individual review x 314 reviewers).

D. Alternatives Considered

1. Medicaid Advisory Committee (MAC)

In determining the best way to promote beneficiary and interested parties' voices in State Medicaid program decision making and administration, we considered several ways of revising the MCAC structure and administration. We considered setting minimum benchmarks for each category of all types of MAC members, but we viewed it as too restrictive. We ultimately concluded that only setting minimum benchmarks (at least 25 percent) for beneficiary representation on the MAC and requiring representation from the other MAC categories would give States maximum flexibility in determining the exact composition of their MAC. However, we understand that some States may want us to set specific thresholds for each MAC category rather than determine those categories on their own.

We also considered having not having a separate BAG, but we ultimately determined that requiring States to establish a separate BAG assures that there is a dedicated forum for States to receive beneficiary input outside of the MAC. In the MAC setting, a beneficiary might not feel as comfortable speaking up among other Medicaid program interested parties. The BAG also provides an opportunity for beneficiaries to focus on the issues that are most important to them, and bring those issues to the MAC.

Finally, we also considered setting specific topics for the MAC to provide feedback.

However, due to the range of issues specific to each State's Medicaid program, we determined it was most conducive to allow States work with their MAC to identify which topics and priority issues would benefit from interested parties' input.

- 2. Home and Community-Based Services (HCBS)
- a. Person-Centered Service Plans, Grievance Systems, Incident Management Systems

We considered whether to codify the existing 86 percent performance level that was outlined in the 2014 guidance for both person-centered service plans and incident management

systems. We did not choose this alternative due to feedback from States and other interested parties of the importance of these requirements, as well as concerns that an 86 percent performance level may not be sufficient to demonstrate that a State has met the requirements.

We considered whether to apply these requirements to section 1905(a) "medical assistance" State Plan personal care, home health, and case management services. We decided against this alternative based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for HCBS delivered under sections 1915(c), (i), (j), and (k) of the Act and because of differences between the requirements of those authorities and section 1905(a) State Plan benefits.

Finally, we considered allowing a good cause exception to the minimum performance level reporting requirements to both the person-centered service plan and the incident management system. We decided against this alternative because the 90 percent performance level is intended to account for various scenarios that might impact a State's ability to achieve these performance levels. Furthermore, there are existing disaster authorities that States could utilize to request a waiver of these requirements in the event of a public health emergency or a disaster.

b. HCBS Payment Adequacy.

We considered several alternatives to the proposed rule. We considered whether the requirements relating to the percent of payments going to the direct care workforce should apply to other services, such as adult day health, habilitation, day treatment or other partial hospitalization services, psychosocial rehabilitation services, and clinic services for individuals with mental illness. We decided against this alternative because the proposed services (homemaker, home health aide, and personal care) are those for which the vast majority of payment should be comprised of compensation for direct care workers and for which there would be low facility or other indirect costs. We also did not include other services for which the percentage might be variable due to the diversity of services included or for which worker

compensation would be reasonably expected to comprise only a small percentage of the payment.

We considered whether to apply these payment adequacy requirements to section 1905(a) "medical assistance" State Plan personal care and home health services, but decided not to, based on State feedback that they do not have the same data collection and reporting capabilities for these services as they do for sections 1915(c), (i), (j), and (k) HCBS.

We considered whether other reporting requirements such as a State assurance or attestation or an alternative frequency of reporting could be used to determine State compliance but determined that the proposed requirement is necessary to demonstrate compliance.

We considered whether to require reporting at the delivery system, HCBS waiver program, or population level but decided against additional levels of reporting because it would increase reporting burden for States without providing additional information necessary for determining whether States meet the requirements at § 441.302(k).

c. Supporting documentation requirements

No alternatives were considered.

d. HCBS Quality Measure Set Reporting

We considered giving States the flexibility to choose which measures they would stratify and by what factors but decided against this alternative as discussed in the Mandatory Medicaid and CHIP Core Set Reporting proposed rule (see 87 FR 51313). We believe that consistent measurement of differences in health outcomes between different groups of beneficiaries is essential to identifying areas for intervention and evaluation of those interventions.²⁶⁸
Consistency could not be achieved if each State made its own decisions about which data, it would stratify and by what factors.

3. Payment Rate Transparency

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²⁶⁸ Schlotthauer AE, Badler A, Cook SC, Perez DJ, Chin MH. Evaluating Interventions to Reduce Health Care Disparities: An RWJF Program. Health Aff (Millwood). 2008;27(2):568-573.

In developing this proposed rule, we considered multiple alternatives. We considered not proposing this rule and maintaining the status quo under current regulations at § 447.203 and 204. However, as noted throughout the Background and Provisions sections of this rule, since the 2011 proposed rule, we have received concerns from interested parties, including State agencies, about the administrative burden of completing AMRPs and questioning whether they are the most efficient way to determine access to care. These comments expressed particular concern about the AMRPs' value when they are required to accompany a proposed nominal rate reduction or restructuring, or where proposed rate changes are made via application of a previously approved rate methodology. At the same time, and as we have discussed, the Supreme Court's 2015 decision in Armstrong v. Exceptional Child Care, Inc., 135 S. Ct. 1378 (2015) ruled that Medicaid providers and beneficiaries do not have private right of action to challenge State-determined Medicaid payment rates in Federal courts. This decision emphasized a greater importance on our administrative review of SPAs proposing to reduce or restructure payment rates. For both of these reasons, this proposed rule includes proposals that would create an alternative process that both reduces the administrative burden on States and standardizes and strengthens our review of proposed payment rate reductions or payment restructurings to ensure compliance with section 1902(a)(30)(A) of the Act.

We considered, but did not propose, adopting a complaint-driven process or developing a Federal review process for assessing access to care concerns. Although such processes could further our goals of ensuring compliance with the access requirement in section 1902(a)(30)(A) of the Act, we concluded similar effects could be achieved through methods that did not require the significant amount of Federal effort that would be necessary to develop either or both of these processes. Additionally, a complaint-driven process would not necessarily ensure a balanced review of State-proposed payment rate or payment structure changes, and it is possible that a large volume of complaints could be submitted with the intended or unintended effect of hampering State Medicaid program operations. Therefore, the impact of adopting a

complaint-driven process or developing a Federal review process for assessing access to care concerns may be negligible given existing processes. Instead, we believe that relying on existing processes that States are already engaged in, such as the ongoing provider and beneficiary feedback channels under paragraph (b)(7) in § 447.203 and the public process requirement for States submitting a SPA that proposed to reduce or restructure Medicaid service payments in § 447.204, would be more effective than creating a new process. While we are relying on existing public feedback channels and processes that States are already engaged in, we are seeking public comment regarding our alternative consideration to propose adopting a complaint driven process or developing a Federal review process for assessing access to care concerns.

We considered finalizing the 2018 proposed rule that would have provided exemptions to the AMRP process for States with high managed care penetration or finalizing the 2019 proposed rule that would have rescinded the AMRP requirements without substantive replacement. As described in the 2018 proposed rule, while we agreed that our experience implementing the AMRP process from the 2015 final rule with comment period raised questions about the benefit of the access analysis when States proposed nominal payment rate reductions or payment restructurings that were unlikely to result in diminished access to care, we did not believe maintaining the AMRP process was the best course of action. ²⁶⁹ Additionally, after proposing to rescind the AMRP requirements through the 2019 proposed rule and issuing a CMCS Informational Bulletin about an agency wide effort to establish a new, comprehensive access strategy, we decided not to rescind the AMRP requirements without another regulation in place to codify the requirements for State compliance with section 1902(a)(30)(A) of the Act given our oversight responsibility. While we have already received and reviewed public comments received on the 2018 proposed rule or the 2019 proposed rule, we are seeking any additional public comments that were not already captured during the comment periods of the 2018

proposed rule or 2019 proposed rule with regard to finalizing these rules as an alternative considered within this proposed rulemaking.

We considered numerous variations of the individual provisions of this proposed rule. We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type, calculate an average Medicaid payment rate of all providers for each E/M CPT code subject to the comparative payment rate analysis. We also considered, but did not propose, different points of comparison other than Medicare under the comparative payment rate analysis proposed under § 447.203(b)(2) or using a peer payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate under the comparative payment rate analysis proposed under § 447.203(b)(2) and (3). We considered, but did not propose, varying timeframes for the comparative payment rate analysis proposed under § 447.203(b)(2). We also considered not proposing the payment rate transparency aspect of this rule proposed under § 447.203(b)(1), leaving the comparative payment rate analysis to replace the AMRP process as proposed under § 447.203(b)(2). With regard to the proposal in § 447.203(c), we considered, but did not propose, establishing alternative circumstances from those described in the 2017 SMDL for identifying nominal payment rate adjustments, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring, using measures that are different from the proposed measures that would be reflected in the forthcoming template, allowing States to use their own unstructured data for

States that fail to meet all three criteria in § 447.203(c)(1), and CMS producing and publishing the comparative payment rate analysis proposed in § 447.203(b).

We considered, but did not propose, maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis proposed under § 447.203(b)(2). Maintaining the benefits in current § 447.203(b)(5)(ii)(A) through (H) would have simplified the transition from the AMRP process to the payment rate transparency and comparative payment rate analysis requirements, if this proposed rule is finalized. However, our experience implementing the 2015 final rule with comment period, as well as interested parties' and States' feedback about the AMRP process, encouraged us to review and reconsider the current list of benefits subject to the AMRP process under current regulations § 447.203(b)(5)(ii)(A) through (H) to determine where we could decrease the level of effort required from States while still allowing ourselves an opportunity to review for access concerns. During our review of the current list of benefits under § 447.203(b)(5)(ii)(A) through (H), we considered, but did not propose, requiring all mandatory Medicaid benefit categories be included in the comparative payment rate analysis. However, when considering the existing burden of the AMRP process under current § 447.203)(b), we believed that expanding the list of benefits to include under proposed § 447.203(b) and (c) would not support our goal to develop a new access strategy that aims to balance Federal and State administrative burden with our shared obligation to ensure compliance with section 1902(a)(30)(A) of the Act. As previously noted section II, of this rule, we are seeking public comment on primary care services, obstetrical and gynecological services, outpatient behavioral health services, and personal care, home health aide, and homemaker services provided by individual providers and providers employed by an agency as the proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2)(i). Additionally, we are seeking public comment regarding our alternative consideration to propose

maintaining the benefits outlined in the current § 447.203(b)(5)(ii)(A) through (H) or propose requiring all mandatory Medicaid benefit categories.

We also considered, but did not propose, including inpatient hospital behavioral health services and covered outpatient drugs including professional dispensing fees as additional categories of services subject to the comparative payment rate analysis proposed under § 447.203(b)(2). As previously described in section II. Of this proposed rule, we did not propose including inpatient behavioral health services as an additional category of service in the comparative payment rate analysis due to existing UPL and CAA payment data requirements for institutional services. The impact of including inpatient behavioral health services in the comparative payment rate analysis would have required duplicative effort by States to report the same information in a different format to us. Additionally, we considered, but did not propose, including covered outpatient drugs (including professional dispensing fees) as an additional category of service in the comparative payment rate analysis due to the complexity of drug pricing policies and use of rebate programs that does not fit into our proposed comparative payment rate analysis methodology that relies on E/M CPT/HCPCS codes to identify the services subject to the analysis. ²⁷⁰ The impact of including covered outpatient drugs (including professional dispensing fees) in the comparative payment rate analysis would have resulted in us proposing an entirely different process, in addition to the comparative payment rate analysis, for States to follow which would create additional burden on States to comply with. However, we are still seeking public comment regarding our decision not to include inpatient behavioral health services and covered outpatient drugs including professional dispensing fees as additional proposed categories of services subject to the comparative payment rate analysis requirements in proposed § 447.203(b)(2).

We considered, but did not propose, requiring States whose Medicaid payment rates vary by provider type to calculate an average Medicaid payment rate of all provider types for each

²⁷⁰ https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/.

E/M CPT code subject to the comparative payment rate analysis. Rather than proposing States distinguish their Medicaid payment rates by each provider type in the comparative payment rate analysis, we considered proposing States calculate an average Medicaid payment rate of all providers for each E/M CPT code. This consideration would have simplified the comparative payment rate analysis because States would include a single, average Medicaid payment rate amount and only need to separately analyze their Medicaid payment rates for services delivered to pediatric and adult populations, if they varied. However, calculating an average for the Medicaid payment rate has limitations, including sensitivity to extreme values and inconsistent characterizations of the payment rate between Medicaid and Medicare. In this rule, we propose to characterize the Medicare payment rate as the non-facility payment rate listed on the Medicare PFS for the E/M CPT/HCPCS codes subject to the comparative payment rate analysis. If we were to propose the Medicaid payment rate be calculated as an average Medicaid payment rate of all provider types for the same E/M CPT/HCPCS code, then States' calculated average Medicaid payment rate could include a wide variety of provider types, from a single payment rate for physicians to an average of three payment rates for physicians, physician assistants, and nurse practitioners. This wide variation in how the Medicaid payment rate is calculated among States would provide a less meaningful comparative payment rate analysis to Medicare. The extremes and outliers that would be diluted by using an average are not necessarily the same for both Medicaid and Medicare, so even if both sides of the comparison used an average, we would not be able to look more closely at specific large differences between the respective rates. As previously noted in section II. of this proposed rule, we are seeking public comment on the proposed characterization of the Medicaid payment rate, which accounts for variation in payment rates for pediatric and adult populations and distinguishes payment rates by provider type, in the comparative payment rate analysis. Additionally, we are seeking public comment regarding our alternative consideration to propose requiring States whose Medicaid payment rates vary by

provider type to calculate an average Medicaid payment rate of all provider types for each E/M CPT code subject to the comparative payment rate analysis.

We considered, but did not propose, requiring States to use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer, such as pediatric dental services or HCBS. The impact of requiring a different point of comparison, other than Medicare, would have carried forward the current regulation requiring States to "include an analysis of the percentage comparison of Medicaid payment rates to other public (including, as practical, Medicaid managed care rates) and private health insurer payment rates within geographic areas of the State" in their AMRPs. As previously discussed in this rule, FFS States expressed concerns following the 2015 final rule with comment period that private payer payment rates were proprietary information and not available to them, therefore, the challenges to comply with current regulations would be carried forward into the proposed rule. Therefore, we also considered, but did not propose, using various payment rate benchmarking approaches for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. As previously noted in section II. of this proposed rule, we considered benchmarks based on national Medicaid payment averages for certain services included within the LTSS benefit category, benchmarks that use average daily rates for certain HCBS that can be compared to other State Medicaid programs, and benchmarks that use payment data specific to the State's Medicaid program for similarly situated services so that the service payments may be benchmarked to national average. Notwithstanding the previously described limitations of the alternative considered for situations where differences between Medicaid and Medicare coverage and payment exists, we are seeking public comment regarding our alternative consideration to propose States use a different point of comparison, other than Medicare, for certain services where Medicare is not a consistent or primary payer or States use a payment rate benchmarking approach for benefit categories where Medicaid is the only or primary payer, or there is no comparable Medicare rate. Specifically, we are seeking public

comment on the feasibility and burden on States to implement these alternatives considered for the proposed comparative payment rate analysis. For any comparison to other State Medicaid programs or to a national benchmark, we also are seeking public comment on the appropriate role for such a comparison in the context of the statutory requirement to consider beneficiary access relative to the general population in the geographic area.

We considered, but did not propose, various timeframes for the comparative payment rate analysis, including annual (every year), triennial (every 3 years), or quinquennial (every 5 years) updates after the initial effective date of January 1, 2026. As noted in section II. of this proposed rule, we did not propose an annual timeframe as we felt that an annual update requirement was too frequent due to many State's biennial legislative sessions that provide the Medicaid agency with authority it make Medicaid payment rate changes as well as create more or maintain a similar level of administrative burden of the AMRPs. While some States do have annual legislative sessions and may have annual Medicaid payment rate changes, we felt that proposing annual updates solely for the purpose of capturing payment rate changes in States that with annual legislative sessions would be overly burdensome and duplicative for States with biennial legislative sessions who do not have new, updated Medicaid payment rates to update in their comparative payment rate analysis. Therefore, for numerous States with biennial legislative sessions, the resulting analysis would likely not vary significantly from year to year. Additionally, the comparative payment rate analysis proposes to use the most recently published Medicare payment rates and we are cognizant that Medicare payment rate updates often occur on a quarterly basis. While Medicare often increases rates by the market basket inflation amount, as well as through rulemaking, it does not always result in payment increases for providers. ^{271,272}

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²⁷¹ Although "market basket" technically describes the mix of goods and services used in providing health care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term "market basket" as used in this document refers to the various CMS input price indexes. A CMS market basket is described as a fixed-weight, Laspeyres-type index because it measures the change in price, over time, of the same mix of goods and services purchased in the base period. FAQ – Medicare Market Basket Definitions and General Information, updated May 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/info.pdf Accessed January 4, 2023.

²⁷² Medicare Unit Cost Increases Reported as of April 2022. https://www.cms.gov/files/document/ffs-trends-2021-2023-april-2022.pdf. Accessed January 4, 2023.

We also considered, but did not propose, maintaining the triennial (every 3 years) timeframe currently in regulation, because we thought it necessary to make significant changes to the non-SPA-related reported in § 447.203(b) that would represent a significant departure from the initial AMRP process in the 2015 final rule with comment in the current § 447.203(b)(1) and this new proposed approach did not lend itself to the triennial timeframe of the current AMRP process. Lastly, we considered, but did not propose, the comparative payment rate analysis be published on a quinquennial basis (every 5 years), because this timeframe was too infrequent for the comparative payment rate analysis to provide meaningful, actionable information. As previously noted in section II. of this rule, we are seeking public comment on the proposed timeframe for the initial publication and biennial update requirements of the comparative payment rate analysis as proposed in § 447.203(b)(4). Additionally, we are seeking public comment regarding our alternative consideration to propose an annual, triennial, or quinquennial timeframe for the updating the comparative payment rate analysis after the initial effective date.

We considered, but did not propose, requiring the comparative payment rate analysis be submitted directly to us, as this would not achieve the public transparency goal of the proposed rule. As proposed in § 447.203(b)(3), we are requiring States develop and publish their Medicaid comparative payment rate analysis on the State's website in an accessible and easily understandable format. This proposal is methodologically similar to the current regulation, which requires AMRPs be submitted to us and publicly published by the State and CMS. We found this aspect of the rule to be an effective method of publicly sharing access to care information, as well as ensuring State compliance. As previously noted in section II. of this proposed rule, we are seeking public comment on the proposed requirement for States to publish their Medicaid FFS payment rates for all services and comparative payment rate analysis and payment rate disclosure information on the State's website under the proposed § 447.203(b)(1) and (3), respectively. Additionally, we are seeking public comment regarding our alternative

consideration to propose requiring the comparative payment rate analysis be submitted directly to us and not publicly published.

We considered, but did not propose, that we produce and publish the comparative payment rate analysis proposed in § 447.203(b)(2) through (3) whereby we would develop reports for all States demonstrating Medicaid payment rates for all services or a subset for Medicaid services as a percentage of Medicare payment rates. Shifting responsibility for this analysis would remove some burden from States and allow us to do a full cross-comparison of State Medicaid payment rates to Medicare payment rates, while ensuring a consistent rate analysis across States. However, this approach would rely on T-MSIS data, which would increase the lag in available data due to the need for CMS to prepare it, and introduce uncertainty into the results due to ongoing variation in State T-MSIS data quality and completeness. Although our proposed approach still relies on State-supplied data, they are able to perform the comparisons on their own regardless of the readiness and compliance of any other State. Furthermore, we would need to validate its results with States and work through any discrepancies. Ultimately, we determined the increased lag time and uncertainty in results would diminish the utility of the rate analyses proposed in § 447.203(b), if performed by us instead of the States, to support our oversight of State compliance with section 1902(a)(30)(A) of the Act. As previously noted in section II. of this rule, we are seeking public comment on our proposal to require States to develop and publish a comparative payment rate analysis and payment rate disclosure as proposed in § 447.203(b)(2) and (3). Additionally, we are seeking public comment regarding our alternative consideration to propose that we produce and publish the comparative payment rate analysis and payment rate disclosure proposed in § 447.203(b)(2) and (3) for all States.

We considered, but did not propose, establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring. We previously outlined in SMDL #17-004 several circumstances where Medicaid

payment rate reductions generally would not be expected to diminish access: reductions necessary to implement CMS Federal Medicaid payment requirements; reductions that will be implemented as a decrease to all codes within a service category or targeted to certain codes, but for services where the payment rates continue to be at or above Medicare and/or average commercial rates; and reductions that result from changes implemented through the Medicare program, where a State's service payment methodology adheres to the Medicare methodology. This proposed rule would not codify this list of policies that may produce payment rate reductions unlikely to diminish access to Medicaid-covered services. We considered, but did not propose, setting a different percentage for the criteria that State Medicaid rates for each benefit category affected by the reductions or restructurings must, in the aggregate, be at or above 80 percent of the most recent comparable Medicare payment rates after the proposed reduction or restructuring as a threshold. We considered setting the threshold at 100 percent of Medicare to remain consistent with the 2017 SMDL. However, after conducting a literature review, we determined that 80 percent of the most recently published Medicare payment rates is currently the most reliable benchmark of whether a rate reduction or restructuring is likely to diminish access to care. We also considered, but did not propose, setting a different percentage for the criteria that proposed reductions or restructurings result in no more than 4 percent reduction of overall FFS Medicaid expenditures for a benefit category. We considered a variety of percentages, but determined that codifying the 4 percent threshold from the 2017 SMDL and proposed in the 2018 proposed rule²⁷³ was the best option based on our experience implementing this established policy after the publication of the 2017 SMDL. Additionally, we received a significant number of comments in the 2018 proposed rule from State Medicaid agencies that signaled strong support for this percentage threshold as a meaningful threshold for future rate

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²⁷³ 83 FR 12696 at 12705.

changes. 274 275 276 Lastly, we considered, but did not propose, defining what is meant by "significant" access concerns received through the public process described in § 447.204 when a State proposes a rate reduction or restructuring. As proposed, we expect State Medicaid agencies to make reasonable determinations about which access concerns are significant when raised through the public process, and as part of our SPA review, may request additional information from the State to better understand any access concerns that have been raised through public processes and whether they are significant. Based on our experience implementing the policies outlined in the 2017 SMDL and a literature review of relevant research about payment rate sufficiency, we proposed criteria for States proposing rate reductions or restructurings that would reduce the SPA submission requirements when those criteria are met. Additionally, each of these thresholds is one of a three-part test where States must meet all three, or else it will trigger a requirement for additional State analysis of the rate reduction or restructuring. As previously noted in section II. of this rule, we are seeking public comment on the streamlined criteria proposed in § 447.203(c)(1). Additionally, we are seeking public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, establishing a minimum set of required data for States above 80 percent of the most recent Medicare payment rates after the proposed reduction or restructuring regardless of the remaining criteria. This requirement would minimize administrative burden on States by not requiring States submit all items in § 447.203(c)(2) and establish a baseline for comparison if future rate reductions or restructurings are proposed that may lower the State's payment rates below 80 percent of the most recent Medicare payment

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²⁷⁴ Connecticut Department of Social Services, Comment Letter on 2018 Proposed Rule (May 21, 2018), https://downloads.regulations.gov/CMS-2018-0031-0021/attachment 1.pdf.

²⁷⁵ California Department of Health Care Services, Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0090/attachment 1.pdf.

²⁷⁶ Florida Agency for Health Care Administration, Comment Letter on 2018 Proposed Rule (May 24, 2018), https://downloads.regulations.gov/CMS-2018-0031-0083/attachment 1.pdf.

rates. However, we determined that, while we believe 80 percent to be an effective threshold point, we did not want that to serve as the only trigger for additional analysis. As proposed, only States that do not meet all of the proposed requirements in § 447.203(c)(1) will have to submit the required data outlined in § 447.203(c)(2). As previously noted in section II. of this rule, we are seeking public comment on our proposal to require all three criteria described in § 447.203(c)(1)(i) through (iii) for assessing the effect of a proposed payment rate reduction or payment restructuring on access to care. Additionally, we are seeking public comment regarding our alternative consideration to propose establishing alternative circumstances from the 2017 SMDL for identifying nominal payment rate adjustments when States propose a rate reduction or restructuring.

We considered, but did not propose, allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1), thereby eliminating the need for us to develop a template for States proposing rate reductions or restructurings. While this would reduce administrative burden on us and provide States with flexibility in determining relevant data for complying with statutory and regulatory requirements, we received feedback after the 2015 final rule with comment period that States found developing an AMRP from scratch with minimal Federal guidelines a challenging task and other interested parties noted that States had too much discretion in documenting sufficient access to care. Therefore, we proposed developing a template to support State analyses of rate reduction or restructuring SPAs that fail to meet the criteria in § 447.203(c)(1). As noted elsewhere in the preamble, if finalized, we anticipate releasing subregulatory guidance, including a template to support completion of the analysis that would be required under paragraph (c)(2), prior to the beginning date of the Comparative Payment Rate Analysis and Payment Rate Disclosure Timeframe proposed in § 447.203(b)(4), which is proposed to begin 2 years after the effective date of the final rule. In the intervening period, we anticipate working directly with States through the SPA review process to ensure compliance with section 1902(a)(30)(A) of the Act.

Additionally, we are seeking public comment regarding our alternative consideration to propose allowing States to use their own unstructured data, similar to the AMRP process, for States that fail to meet all three criteria in § 447.203(c)(1).

After careful consideration, we ultimately determined that the requirements in proposed § 447.203(b) and (c) would strike a more optimal balance between alleviating State and Federal administrative burden, while ensuring a transparent, data-driven, and consistent approach to States' implementation and our oversight of State compliance with the access requirement in section 1902(a)(30)(A) of the Act.

E. Accounting Statement and Table

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 43 showing the classification of the impact associated with the provisions of this proposed rule. Note, Table 43 shown previously in this proposed rule provides a summary of the one-time and annual costs estimates.

TABLE 44: Accounting Table

		Units		
Category	Estimates	Year Dollar	Discount Rate	Period Covered
Regulatory Review Costs				
Annualized Monetized	.112	2023	7%	2024 - 2028
(\$million/year)	.117	2023	3%	2024 - 2028
Costs to States				
Annualized Monetized	72.12	2023	7%	2024 - 2028
(\$million/year)	75.22	2023	3%	2024 - 2028
Costs to Beneficiaries				
Annualized Monetized	0.47	2023	7%	2024 - 2028
(\$million/year)	0.49	2023	3%	2024 - 2028
Costs to Providers				
Annualized Monetized	102.05	2023	7%	2024 - 2028
(\$million/year)	106.44	2023	3%	2024 - 2028
Costs to Managed Care Entities				
Annualized Monetized	6.84	2023	7%	2024 - 2028
(\$million/year)	7.13	2023	3%	2024 - 2028

F. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA,

we estimate that *almost all* of Home Health Care Services, Services for the Elderly and Persons with Disabilities, and Direct Health and Medical Insurance Carriers are small entities as that term is used in the RFA (include small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year).

For purposes of the RFA, approximately 95 percent of the health care industries impacted are considered small businesses according to the Small Business Administration's size standards with total revenues of \$41 million or less in any 1 year.

According to the SBA's website at http://www.sba.gov/content/small-business-size-standards HCBS Provider Costs and Managed care Entity fall in the North American Industrial Classification System 621610 Home Health Care Services, 624120 Services for the Elderly and Persons with Disabilities, and 524114 Direct Health and Medical Insurance Carriers.

TABLE 45: HCBS Providers Costs And Managed Care Entity Size Standards

NAICS		SBA Size Standard/	Total Small		
(6-digit)	Industry Subsector Description	Small Entity Threshold	Businesses		
621610	Home Health Care Services	\$15 Million	20,597		
	Services for the Elderly and Persons				
624120	with Disabilities	\$19 Million	20,740		
	Direct Health and Medical Insurance				
524114	Carriers	\$47 Million	501		

Source: 2012 Economic Census. Note, no recent data exist for Enterprise Receipt Size.

Individuals and States are not included in the definition of a small entity. This rule will not have a significant impact measured change in revenue of 3 to 5 percent on a substantial number of small businesses or other small entities. All the industries combined, according to the 2012 Economic Census, earned approximately \$46,771,961,000.00. Hence, all the costs combined, amounts to about 1 percent.

Therefore, as its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule. Therefore, the Secretary has

certified that this proposed will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the Act. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule will not have a significant impact on the operations of small rural hospitals since small hospitals are not affected by the proposed rule. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2023, that threshold is approximately \$177 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$177 million in any 1 year.

Several of the provisions in the proposed rule address gaps in existing regulations. In these cases, the costs for States to implement those proposals would be minimal. For the remaining areas of the proposed rule, we have sought to minimize burden whenever possible while still achieving the goals of this rulemaking. We further note that, if finalized, States would be able to claim administrative match for the work required to implement the proposals.

H. Federalism

EO 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule does not impose

substantial direct costs on State or local governments, preempt State law, or otherwise have Federalism implications. As mentioned in the previous section of this rule, the costs to States by our estimate do not rise to the level of specified thresholds for significant burden to States. In addition, many proposals amend existing requirements or further requirements that already exist in statute, and as such would not create any new conflict with State law.

I. Conclusion

If the policies in this proposed rule are finalized, it will enable us to implement enhanced access to health care services for Medicaid beneficiaries across FFS, managed care, and HCBS delivery systems.

The analysis in section V. of this proposed rule, together with the rest of this preamble, provides a regulatory impact analysis. In accordance with the provisions of EO 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on XX XX, 20XX

List of Subjects

42 CFR Part 431

Administrative practice and procedure, Consumer protection, Grant programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirement.

42 CFR Part 438

Administrative practice and procedure, Grant programs-health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements. 42 CFR Part 441

Administrative practice and procedure, Consumer_protection, Grant programs-health, Health professions, Medicaid, Older adults, People with Disabilities, Reporting and recordkeeping requirements

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs- health,
Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, and
Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

1. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 1302.

2. Revise § 431.12 to read as follows:

§ 431.12 Medicaid Advisory Committee and Beneficiary Advisory Group

- (a) Basis and purpose. This section, based on section 1902(a)(4) of the Act, prescribes State Plan requirements for establishment and ongoing operation of a public Medicaid Advisory Committee (MAC) with a dedicated Beneficiary Advisory Group (BAG) comprised of current and former Medicaid beneficiaries, their family members and caregivers, to advise the State Medicaid agency on matters of concern related to policy development, and matters related to the effective administration of the Medicaid program.
- (b) State plan requirement. The State Plan must provide for a MAC and a BAG that will advise the Medicaid Agency Director on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.
- (c) Appointment of members. The agency director, or a higher State authority, must appoint members to the MAC and BAG on a rotating and continuous basis. The State must create a process for recruitment and appointment of members and publish this information on the States website as specified in paragraph (f).
- (d) MAC membership and composition. The membership of the MAC must be composed of the following percentage and representative categories of interested parties in the State:
 - (1) Minimum of 25 percent of committee members must be from the BAG.
- (2) The remaining committee members must include representation of at least one from each of the following categories:

- (A) State or local consumer advocacy groups or other community-based organizations that represent the interests of, or provide direct service, to Medicaid beneficiaries.
- (B) Clinical providers or administrators who are familiar with the health and social needs of Medicaid beneficiaries and with the resources available and required for their care. This includes providers or administrators of primary care, specialty care, and long-term care.
- (C) Participating Medicaid managed care plans, or the State health plan association representing such plans, as applicable; and
- (D) Other State agencies that serve Medicaid beneficiaries (for example, foster care agency, mental health agency, health department, State agencies delegated to conduct eligibility determinations for Medicaid, State Unit on Aging), as ex-officio members.
- (e) *Beneficiary Advisory Group*. The State must form and support a BAG, which can be an existing beneficiary group, that is comprised of: Individuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid), to advise and provide input to the State regarding their experience with the Medicaid program, on matters of concern related to policy development and matters related to the effective administration of the Medicaid program.
- (1) The MAC members described in paragraph (d)(1) of this section must also be members of the BAG.
- (2) The BAG must meet separately from the MAC, on a regular basis, and in advance of each MAC meeting to ensure BAG member preparation for each MAC meeting.
- (f) MAC and BAG administration. The State agency must create standardized processes and practices for the administration of the MAC and the BAG that are available for public review on the State website. The State agency must –
- (1) Develop and publish by posting publicly on its website, bylaws for governance of the MAC and BAG, a current list of MAC and BAG membership, and past meeting minutes of the MAC and BAG meetings, including a list of meeting attendees;

- (2) Develop and publish by posting publicly on its website a process for MAC and BAG member recruitment and appointment and selection of MAC and BAG leadership;
- (3) Develop, publish by posting publicly on its website, and implement a regular meeting schedule for the MAC and BAG; the MAC and BAG must each meet at least once per quarter and hold off-cycle meetings as needed.
- (4) Make at least two MAC meetings per year open to the public and those meetings must include a dedicated time during the meeting for the public to make comments. The public must be adequately notified of the date, location, and time of each public MAC meeting at least 30 calendar days in advance. BAG meetings are not required to be open to the public, unless the State's BAG members decide otherwise. The same requirements would apply to States whose BAG meetings were determined, by its membership, to be open to the public;
- (5) Offer a variety of in-person and virtual attendance options including, at a minimum telephone dial-in options at the MAC and BAG meetings for its members. If the MAC or BAG meeting is deemed open to the public, the State must offer at a minimum a telephone dial-in option for members of the public;
- (6) Ensure meeting times and locations for MAC and BAG meetings are selected to maximize member attendance and may vary by meeting; and
- (7) Facilitate participation of beneficiaries by ensuring that that meetings are accessible to people with disabilities, that reasonable modifications are provided when necessary to ensure access and enable meaningful participation, and communications with individuals with disabilities are as effective as with others, that reasonable steps are taken to provide meaningful access to individuals with Limited English Proficiency, and that meetings comply with the requirements at § 435.905(b) of this chapter and applicable regulations implementing the ADA, section 504 of the Rehabilitation Act, and section 1557 of the Affordable Care Act at 28 CFR part 35 and 45 CFR parts 84 and 92.

- (g) MAC and BAG participation and scope. The MAC and BAG participants must have the opportunity to participate in and provide recommendations to the State agency on matters related to policy development and matters related to the effective administration of the Medicaid program. At a minimum, the MAC and BAG must determine, in collaboration with the State, which topics to provide advice on related to -
 - (1) Additions and changes to services;
 - (2) Coordination of care;
 - (3) Quality of services;
 - (4) Eligibility, enrollment, and renewal processes;
- (5) Beneficiary and provider communications by State Medicaid agency and Medicaid managed care plans;
- (6) Cultural competency, language access, health equity, and disparities and biases in the Medicaid program; or
- (7) Other issues that impact the provision or outcomes of health and medical care services in the Medicaid program as by the MAC, BAG, or State.
- (h) State agency staff assistance, participation, and financial help. The State agency must provide staff to support planning and execution of the MAC and the BAG to include -
 - (1) Recruitment of MAC and BAG members;
- (2) Planning and execution of all MAC and BAG meetings and the production of meeting minutes that include actions taken or anticipated actions by the State in response to interested parties' feedback provided during the meeting. The minutes are to be posted on the State's website within 30 calendar days following each meeting. Additionally, the State must also produce and post on its website an annual report as specified in paragraph (i) of this section; and

- (3) The provision of appropriate support and preparation (providing research or other information needed) to the Medicaid beneficiary MAC and BAG members to ensure meaningful participation. These tasks include –
- (i) Providing staff whose responsibilities include facilitating MAC and BAG member engagement;
- (ii) Providing financial support, if necessary, to facilitate Medicaid beneficiary engagement in the MAC and the BAG.
- (iii) Attendance by at least one staff member from the State agency's executive staff at all MAC and BAG meetings.
- (i) *Annual report*. The MAC, with support from the State, submit an annual report describing its activities, topics discussed, and recommendations. The State must review the report and include responses to the recommended actions. The State agency must then
 - (1) Provide MAC members with final review of the report;
- (2) Ensure that the annual report of the MAC includes a section describing the activities, topics discussed, and recommendations of the BAG, as well as the State's responses to the recommendations; and
 - (3) Post the report to the State's website.
- (j) Federal financial participation. FFP is available at 50 percent of expenditures for the MAC and BAG activities.
 - 3. Amend § 431.408 by revising paragraph (a)(3)(i) to read as follows:

§ 431.408 State public notice process.

- (a) * * *
- (3) * * *
- (i) The Medicaid Advisory Committee and Beneficiary Advisory Group that operate in accordance with § 431.12 of this subpart; or

PART 438—MANAGED CARE

4. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

5. Section 438.72 is added to subpart B to read as follows:

§ 438.72 Additional requirements for long-term services and supports.

- (a) [Reserved]
- (b) Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities. The State must comply with the review of the person-centered service plan requirements at § 441.301(c)(1) through (3), the incident management system requirements at § 441.302(a)(6), the payment adequacy requirements at § 441.302(k), the reporting requirements at § 441.311, and the website transparency requirements at § 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

PART 441— SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

6. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

7. Amend § 441.301 by revising paragraphs (c)(1) and (3), and adding paragraph (c)(7) to read as follows:

§ 441.301 Contents of request for a waiver.

* * * * *

- (c) * * *
- (1) *Person-centered planning process*. The individual, or if applicable, the individual and the individual's authorized representative, will lead the person-centered planning process. When the term "individual" is used throughout this section, it includes the individual's authorized representative if applicable. In addition, the person-centered planning process:

- (3) Review of the person-centered service plan--(i) Requirement. The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required by § 441.365(e), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.
- (ii) *Minimum performance at the State level*. The State must demonstrate, through the reporting requirements at § 441.311(b)(3), that it meets the following minimum performance levels:
- (A) Complete a reassessment of functional need at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days; and
- (B) Review and revise, as appropriate, the person-centered service plan, based upon the reassessment of functional need, at least every 12 months for no less than 90 percent of the individuals continuously enrolled in the waiver for at least 365 days.
- (iii) Effective date. The performance levels described in paragraph (c)(3)(ii) of this section are effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

- (7) *Grievance system--*(i) *Purpose*. The State must establish a procedure under which a beneficiary may file a grievance related to the State or a provider's compliance with paragraphs (c)(1) through (6) of this section. This requirement does not apply to a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.
 - (ii) Definitions. As used in this section:

Grievance means an expression of dissatisfaction or complaint related to the State's or a provider's compliance with paragraphs (c)(1) through (6), regardless of whether remedial action is requested.

Grievance system means the processes the State implements to handle grievances, as well as the processes to collect and track information about them.

- (iii) *General requirements*. (A) The beneficiary or a beneficiary's authorized representative, if applicable, may file a grievance. All references to beneficiary include the role of the beneficiary's representative, if applicable.
- (1) Another individual or entity may file a grievance on behalf of the beneficiary with the written consent of the beneficiary or authorized representative.
- (2) A provider cannot file a grievance that would violate the State's conflict of interest guidelines, as required in § 441.540(a)(5).
 - (B) The State must:
- (1) Base its grievance processes on written policies and procedures that, at a minimum, meet the conditions set forth in this subsection;
- (2) Provide beneficiaries reasonable assistance in completing forms and taking other procedural steps related to a grievance. This includes, but is not limited to, ensuring the grievance system is accessible to individuals with disabilities and persons who are limited English proficient, consistent with § 435.905(b) of this chapter, and includes auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability;
- (3) Ensure that punitive action is neither threatened nor taken against an individual filing a grievance;
- (4) Accept grievances and requests for expedited resolution or extension of timeframes from the beneficiary;

- (5) Provide to the beneficiary the notices and information required under this subsection, including information on their rights under the grievance system and on how to file grievance, and ensure that such information is accessible for individuals with disabilities and individuals who are limited English proficient in accordance with § 435.905(b);
 - (6) Review any grievance resolution with which the beneficiary is dissatisfied; and
- (7) Provide information about the grievance system to all providers and subcontractors approved to deliver services.
 - (C) The process for handling grievances must:
 - (1) Allow the beneficiary to file a grievance with the State either orally or in writing.
 - (2) Acknowledge receipt of each grievance.
 - (3) Ensure that the individuals who make decisions on grievances are individuals:
- (i) Who were neither involved in any previous level of review or decision-making related to the grievance nor a subordinate of any such individual;
- (ii) Who are individuals who have the appropriate clinical and non-clinical expertise, as determined by the State; and
- (iii) Who consider all comments, documents, records, and other information submitted by the beneficiary without regard to whether such information was submitted to or considered previously by the State.
- (4) Provide the beneficiary a reasonable opportunity, face-to-face (including through the use of audio or video technology) and in writing, to present evidence and testimony and make legal and factual arguments related to their grievance. The State must inform the beneficiary of the limited time available for this sufficiently in advance of the resolution timeframe for grievances as specified in paragraphs (c)(7)(v)(B)(1) and (2) of this section.
- (5) Provide the beneficiary their case file, including medical records in compliance with 45 CFR 164.510(b), other documents and records, and any new or additional evidence considered, relied upon, or generated by the State related to the grievance. This information must

be provided free of charge and sufficiently in advance of the resolution timeframe for grievance as specified in paragraphs (c)(7)(v)(B)(I) and (2) of this section.

- (6) Provide beneficiaries, free of charge, with language services, including written translation and interpreter services in accordance with § 435.905(b), to support their participation in grievance processes and their use of the grievance system.
 - (iv) Filing timeframes. (A) A beneficiary may file a grievance at any time.
- (B) The beneficiary may request expedited resolution of a grievance whenever there is a substantial risk that resolution within standard timeframes will adversely affect the beneficiary's health, safety, or welfare, as described in paragraph (c)(7)(v) of this section.
- (v) Resolution and notification--(A) Basic rule. The State must resolve each grievance, and provide notice, as expeditiously as the beneficiary's health, safety, and welfare requires, within State-established timeframes that may not exceed the timeframes specified in this section.
- (B) Specific timeframes—(1) Standard resolution of grievances. For standard resolution of a grievance and notice to the affected parties, the timeframe may not exceed 90 calendar days from the day the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.
- (2) Expedited resolution of grievances. For expedited resolution of a grievance and notice to affected parties, the State must establish a timeframe that is no longer than 14 calendar days after the State receives the grievance. This timeframe may be extended under paragraph (c)(7)(v)(C) of this section.
- (C) Extension of timeframes. (1) The States may extend the timeframes from those in paragraph (c)(7)(v)(B) of this section by up to 14 calendar days if
 - (i) The beneficiary requests the extension; or
- (ii) The State documents that there is need for additional information and how the delay is in the beneficiary's interest.

- (D) *Requirements following extension*. If the State extends the timeframes not at the request of the beneficiary, it must complete all of the following:
 - (1) Make reasonable efforts to give the beneficiary prompt oral notice of the delay.
- (2) Within 2 calendar days of determining a need for a delay, but no later than the timeframes in paragraph (c)(7)(v)(B) of this section, give the beneficiary written notice of the reason for the decision to extend the timeframe.
- (3) Resolve the grievance as expeditiously as the beneficiary's health condition requires and no later than the date the extension expires.
 - (vi) Format of notice--(A) Written notice. The State must establish a method to notify a beneficiary of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 435.905(b) of this chapter.
- (B) *Oral notice*. For notice of an expedited resolution, the State must also make reasonable efforts to provide oral notice.
- (vii) *Recordkeeping*. (A) The State must maintain records of grievances and must review the information as part of its ongoing monitoring procedures.
- (B) The record of each grievance must contain, at a minimum, all of the following information:
 - (1) A general description of the reason for the grievance.
 - (2) The date received.
 - (3) The date of each review or, if applicable, review meeting.
 - (4) Resolution of the grievance, as applicable.
 - (5) Date of resolution, if applicable.
 - (6) Name of the beneficiary for whom the grievance was filed.
- (C) The record must be accurately maintained in a manner available upon request to CMS.

(viii) Effective date. This requirement is effective 2 years after the date of enactment of this paragraph. 8. Amend § 441.302 by-a. Adding paragraph (a)(6); b. Revising paragraph (h); c. Adding new paragraph (k). The additions and revision read as follows: § 441.302 State assurances. (a) * * (6) Assurance that the State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents. (i) *Requirements*. The State must: (A) Define critical incident to include, at a minimum— (1) Verbal, physical, sexual, psychological, or emotional abuse; (2) Neglect; (3) Exploitation including financial exploitation; (4) Misuse or unauthorized use of restrictive interventions or seclusion; (5) A medication error resulting in a telephone call to or a consultation with a poison control center, an emergency department visit, an urgent care visit, a hospitalization, or death; or (6) An unexplained or unanticipated death, including but not limited to a death caused by abuse or neglect. (B) Use an information system, as defined in 45 CFR 164.304 and compliant with 45 CFR part 164, that, at a minimum— (1) Enables electronic critical incident data collection;

(2) Tracking (including of the status and resolution of investigations), and;

- (3) Trending.
- (C) Require providers to report to the State, within State-established timeframes and procedures, any critical incident that occurs during the delivery of services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan, or occurs as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan.
- (D) Use claims data, Medicaid fraud control unit data, and data from other State agencies such as Adult Protective Services or Child Protective Services to the extent permissible under applicable State law to identify critical incidents that are unreported by providers and occur during the delivery of services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan, or occur as a result of the failure to deliver services authorized under section 1915(c) of the Act and as specified in the waiver participant's person-centered service plan.
- (E) Ensure that there is information sharing on the status and resolution of investigations, such as through the use of information sharing agreements, between the State and the entity or entities responsible in the State for investigating critical incidents as defined in § 441.302(a)(6)(i)(A) if the State refers critical incidents to other entities for investigation;
- (F) Separately investigate critical incidents if the investigative agency fails to report the resolution of an investigation within State-specified timeframes; and
- (G) Demonstrate that it meets the requirements in paragraph (a)(6) of this section through the reporting requirement at § 441.311(b)(1).
- (ii) *Minimum performance at the State level*. The State must demonstrate, through the reporting requirements at § 441.311(b)(2), that it meets the following minimum performance levels:
- (A) Initiate an investigation, within State-specified timeframes, for no less than 90 percent of critical incidents;

- (B) Complete an investigation and determine the resolution of the investigation, within State-specified timeframes, for no less than 90 percent of critical incidents; and
- (C) Ensure that corrective action has been completed within State-specified timeframes, for no less than 90 percent of critical incidents that require corrective action.
- (iii) Effective date. This requirement is effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.

* * * * *

(h) *Reporting*. Assurance that the agency will provide CMS with information on the waiver's impact, including the data and information as required in § 441.311.

- (k) *HCBS payment adequacy*. Assurance that payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan.
 - (1) Definitions. As used in this section
 - (i) Compensation means:
- (A) Salary, wages, and other remuneration as defined by the Fair Labor Standards Act and implementing regulations (29 U.S.C. 201 *et seq.*, 29 CFR parts 531 and 778);
- (B) Benefits (such as health and dental benefits, sick leave, and tuition reimbursement); and
- (C) The employer share of payroll taxes for direct care workers delivering services authorized under section 1915(c) of the Act.
 - (ii) Direct care worker means any of the following individuals:

- (A) A registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist who provides nursing services to Medicaid-eligible individuals receiving home and community-based services available under this subpart;
- (B) A licensed or certified nursing assistant who provides such services under the supervision of a registered nurse, licensed practical nurse, nurse practitioner, or clinical nurse specialist;
 - (C) A direct support professional;
 - (D) A personal care attendant;
 - (E) A home health aide; or
- (F) Other individuals who are paid to provide services to address activities of daily living or instrumental activities of daily living, behavioral supports, employment supports, or other services to promote community integration directly to Medicaid-eligible individuals receiving home and community-based services available under this subpart.
- (G) A direct care worker may be employed by a Medicaid provider, State agency, or third party; contracted with a Medicaid provider, State agency, or third party; or delivering services under a self-directed service model.
- (2) *Requirement*. The State must demonstrate, through the reporting requirements at § 441.311(e), that it meets the minimum performance levels in paragraph (k)(3) of this section for the services at § 440.180(b)(2) through (4) that are delivered by direct care workers and authorized under section 1915(c) of the Act.
- (3) *Minimum performance at the State level*. The State must meet the following minimum performance level, calculated as the percentage of total payment for a service represented by total compensation to direct care workers:
- (i) At least 80 percent of all payments with respect to services at § 440.180(b)(2) through(4) must be spent on compensation for direct care workers.
 - (ii) [Reserved]

- (4) Effective date. This requirement is effective 4 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 4 years after the date of enactment of this paragraph.
 - 9. Amend § 441.303 by revising paragraph (f)(6) to read as follows:

§ 441.303 Supporting documentation required.

- * * * * *
- (f) * * *
- (6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment. If the State has a limit on the size of the waiver program and maintains a list of individuals who are waiting to enroll in the waiver program, the State must meet the reporting requirements at § 441.311(d)(1).

* * * * *

10. Section 441.311 is added to subpart G to read as follows:

§ 441.311 Reporting requirements.

(a) Basis and scope. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from time to time find necessary to assure the correctness and verification of such reports. Section 1902(a)(19) of the Act requires States to provide safeguards to assure that eligibility for Medicaid-covered care and services will be determined and provided in a manner that is consistent with simplification, simplicity of administration, and in the best interest of Medicaid beneficiaries. This section

describes the reporting requirements for States for section 1915(c) waiver programs, under the authority at section 1902(a)(6) and (a)(19) of the Act.

- (b) Compliance reporting--(1) Incident management system. As described in § 441.302(a)(6)--
- (i) The State must report, every 24 months, according to the format and specifications provided by CMS, on the results of an incident management system assessment to demonstrate that it meets the requirements in § 441.302(a)(6).
- (ii) CMS may reduce the frequency of reporting to up to once every 60 months for States with incident management systems that are determined by CMS to meet the requirements in § 441.302(a)(6).
- (2) *Critical incidents*, as defined in § 441.302(a)(6)(i)(A). The State must report to CMS annually on the following, according to the format and specifications provided by CMS:
- (i) Number and percent of critical incidents for which an investigation was initiated within State-specified timeframes;
- (ii) Number and percent of critical incidents that are investigated and for which the State determines the resolution within State-specified timeframes;
- (iii) Number and percent of critical incidents requiring corrective action, as determined by the State, for which the required corrective action has been completed within State-specified timeframes.
 - (3) Person-centered planning, as described in § 441.301(c)(1) through (3).
- (i) Percent of beneficiaries continuously enrolled for at least 365 days for whom a reassessment of functional need was completed within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.
- (ii) Percent of beneficiaries continuously enrolled for at least 365 days who had a service plan updated as a result of a re-assessment of functional need within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

- (4) The type, amount, and cost of services provided under the State plan.
- (c) Reporting on the Home and Community-Based Services Quality Measure Set, as described in § 441.312.
 - (1) General rules. The State—
- (i) Must report every other year, according to the format and schedule prescribed by the Secretary through the process for developing and updating the measure set described in § 441.312(d), on all measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) of this subpart.
- (ii) May report on all other measures in the Home and Community-Based Services Quality Measure Set that are not described in § 441.312(d)(1)(ii) and (iii) of this subpart.
- (iii) Must establish, subject to CMS review and approval, State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.
- (iv) May establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set that are not identified by the Secretary pursuant to § 441.312(d)(1)(ii) and (iii) of this subpart and describe the quality improvement strategies that the State will pursue to achieve the performance targets.
- (2) Measures identified per § 441.312(d)(1)(iii) of this subpart will be reported by the Secretary on behalf of the State.
- (3) In reporting on Home and Community-Based Services Quality Measure Set measures, the State may, but is not required to:
- (i) Report on the measures identified by the Secretary pursuant to § 441.312(c) of this subpart for which reporting will be, but is not yet required (that is, reporting has not yet been phased-in).

- (ii) Report on the populations identified by the Secretary pursuant to § 441.312(c) of this subpart for whom reporting will be, but is not yet required.
- (d) *Access reporting*. The State must report to CMS annually on the following, according to the format and specifications provided by CMS:
- (1) Waiver waiting lists. (i) A description of how the State maintains the list of individuals who are waiting to enroll in the waiver program, if the State has a limit on the size of the waiver program, as described in § 441.303(f)(6), and maintains a list of individuals who are waiting to enroll in the waiver program. This description must include, but is not limited to:
- (A) Information on whether the State screens individuals on the list for eligibility for the waiver program;
 - (B) Whether the State periodically re-screens individuals on the list for eligibility; and
 - (C) The frequency of re-screening, if applicable.
- (ii) Number of people on the list of individuals who are waiting to enroll in the waiver program, if applicable.
- (iii) Average amount of time that individuals newly enrolled in the waiver program in the past 12 months were on the list of individuals waiting to enroll in the waiver program, if applicable.
- (2) Access to homemaker services, home health aide, and personal care. (i) Average amount of time from when homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), are initially approved to when services began, for individuals newly approved to begin receiving services within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.
- (ii) Percent of authorized hours for homemaker services, home health aide services, or personal care services, as listed in § 440.180(b)(2) through (4), that are provided within the past 12 months. The State may report this metric for a statistically valid random sample of beneficiaries.

- (e) *Payment adequacy*. The State must report to CMS annually on the percent of payments for certain services, as specified in § 441.302(k)(3)(i), that are spent on compensation for direct care workers, at the time and in the form and manner specified by CMS. The State must report separately for each service and, within each service, must separately report services that are self-directed.
- (1) *Services*. The State must report on payment adequacy for the services at § 440.180(b)(2) through (4) that are authorized under section 1915(c) of the Act.
 - (2) [Reserved]
- (f) Effective date. (1) The reporting requirements at paragraphs (b) through (d) of this section are effective 3 years after the date of enactment of this paragraph; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.
- (2) The reporting requirements at paragraph (e) of this section are effective 4 years after the date of enactment of this paragraph; and in the case of a State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 4 years after the date of enactment of this paragraph.
 - 11. Section 441.312 is added to subpart G to read as follows:

§ 441.312 Home and Community-Based Services Quality Measure Set.

(a) *Basis and scope*. Section 1102(a) of the Act provides the Secretary of HHS with authority to make and publish rules and regulations that are necessary for the efficient administration of the Medicaid program. Section 1902(a)(6) of the Act requires State Medicaid agencies to make such reports, in such form and containing such information, as the Secretary may from time to time require, and to comply with such provisions as the Secretary may from

time to time find necessary to assure the correctness and verification of such reports. This section describes the Home and Community-Based Services Quality Measure Set, which States are required to use in section 1915(c) waiver programs to promote public transparency related to the administration of Medicaid covered HCBS, under the authority at sections 1102(a) and 1902(a)(6) of the Act.

(b) *Definitions*. As used in this subpart—

Attribution rules means the process States use to assign beneficiaries to a specific health care program or delivery system for the purpose of calculating the measures on the Home and Community-Based Services Quality Measure Set.

Home and Community-Based Services Quality Measure Set means the Home and Community-Based Services Quality Measures for Medicaid established and updated at least every other year by the Secretary through a process that allows for public input and comment, including through the **Federal Register**, as described in paragraph (d) of this section.

- (c) Responsibilities of the Secretary. The Secretary shall—
- (1) Identify, and update at least every other year, beginning no later than December 31, 2025 and biennially thereafter, the quality measures to be included in the Home and Community-Based Services Quality Measure Set as defined in paragraph (b) of this section.
- (2) Consult at least every other year with States and other interested parties identified in paragraph (g) of this section to—
- (i) Establish priorities for the development and advancement of the Home and Community-Based Services Quality Measure Set;
- (ii) Identify newly developed or other measures which should be added including to address any gaps in the measures included in the Home and Community-Based Services Quality Measure Set;
- (iii) Identify measures which should be removed as they no longer strengthen the Home and Community-Based Services Quality Measure Set; and

- (iv) Ensure that all measures included in the Home and Community-Based Services

 Quality Measure Set reflect an evidence-based process including testing, validation, and
 consensus among interested parties; are meaningful for States; are feasible for State-level,
 program-level, or provider-level reporting as appropriate.
- (3) In consultation with States, develop and update, at least every other year, the HCBS Quality Measure Set using a process that allows for public input and comment as described in paragraph (d) of this section.
- (d) *Process for developing and updating the HCBS Quality Measure Set.* The process for developing and updating the HCBS Quality Measure Set will address all of the following:
- (1) Identification of all measures in the Home and Community-Based Services Quality Measure Set, including:
- (i) Measures newly added and measures removed from the prior version of the Home and Community-Based Services Quality Measure Set;
 - (ii) The specific measures for which reporting is mandatory;
- (iii) The measures for which the Secretary will complete reporting on behalf of States and the measures for which States may elect to have the Secretary report on their behalf; and
- (iv) The measures, if any, for which the Secretary will provide States with additional time to report, as well as how much additional time the Secretary will provide, in accordance with paragraph (c) of this section.
- (2) Technical information to States on how to collect and calculate the data on the Home and Community-Based Services Quality Measure Set.
- (3) Standardized format and reporting schedule for reporting measure data required under this section.
- (4) Procedures that State agencies must follow in reporting measure data required under this section.

- (5) Identification of the populations for which States must report the measures identified by the Secretary under paragraph (e) of this section, which may include, but is not limited to beneficiaries—
- (i) Receiving services through specified delivery systems, such as those enrolled in a managed care plan or receiving services on a fee-for-service basis;
- (ii) Who are dually eligible for Medicare and Medicaid, including beneficiaries whose medical assistance is limited to payment of Medicare premiums or cost sharing;
 - (iii) Who are older adults;
 - (iv) Who have physical disabilities;
 - (v) Who have intellectual and development disabilities;
 - (vi) Who have serious mental illness; and
 - (vii) Who have other health conditions.
- (6) Technical information on attribution rules for determining how States must report on measures for beneficiaries who are included in more than one population, as described in paragraph (d)(5) of this section, during the reporting period.
- (7) The subset of measures among the measures in the Home and Community-Based Services Quality Measure Set that must be stratified by race, ethnicity, sex, age, rural/urban status, disability, language, Tribal status, or such other factors as may be specified by the Secretary and informed by consultation every other year with States and interested parties in accordance with paragraph (b)(2) and subsection (g) of this section.
- (8) Describe how to establish State performance targets for each of the measures in the Home and Community-Based Services Quality Measure Set.
- (e) *Phasing in of certain reporting*. As part of the process that allows for developing and updating the Home and Community-Based Services Quality Measure Set described in paragraph (d) of this section, the Secretary may provide that mandatory State reporting for certain measures

and reporting for certain populations of beneficiaries will be phased in over a specified period of time, taking into account the level of complexity required for such State reporting.

- (f) Selection of measures for stratification. In specifying which measures, and by which factors, States must report stratified measures consistent with paragraph (d)(7) of this section, the Secretary will take into account whether stratification can be accomplished based on valid statistical methods and without risking a violation of beneficiary privacy and, for measures obtained from surveys, whether the original survey instrument collects the variables necessary to stratify the measures, and such other factors as the Secretary determines appropriate; the Secretary will require stratification of 25 percent of the measures in the Home and Community-Based Services Quality Measure Set for which the Secretary has specified that reporting should be stratified by 3 years after the effective date of these regulations, 50 percent of such measures by 5 years after the effective date of these regulations, and 100 percent of measures by 7 years after the effective date of these regulations.
- (g) Consultation with interested parties. For purposes of paragraph (c)(2) of this section, the Secretary must consult with interested parties as described in this paragraph to include the following:
- (1) State Medicaid Agencies and agencies that administer Medicaid-covered home and community-based services.
- (2) Health care and home and community-based services professionals, including members of the allied health professions who specialize in the care and treatment of older adults, children and adults with disabilities, and individuals with complex medical needs.
- (3) Health care and home and community-based services professionals (including members of the allied health professions), providers, and direct care workers who provide services to older adults, children and adults with disabilities, and individuals with complex medical and behavioral health care needs who live in urban and rural medically underserved

communities or who are members of distinct population sub-groups at heightened risk for poor outcomes.

- (4) Providers of home and community-based services.
- (5) Direct care workers and national organizations representing direct care workers.
- (6) Consumers and national organizations representing older adults, children and adults with disabilities, and individuals with complex medical needs.
- (7) National organizations and individuals with expertise in home and community-based services quality measurement.
- (8) Voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care.
 - (9) Measure development experts.
 - (10) Such other interested parties as the Secretary may determine appropriate.
 - 12. Section 441.313 is added to subpart G to read as follows:

§ 441.313 Website transparency.

- (a) The State must operate a website consistent with § 435.905(b) of this chapter that provides the results of the reporting requirements specified at § 441.311. The State must:
- (1) Include all content on one web page, either directly or by linking to individual managed care organization, prepaid ambulatory health plan, prepaid inpatient health plan, and primary care case management, as defined in part 438, entity websites;
 - (2) Include clear and easy to understand labels on documents and links;
- (3) Verify no less than quarterly, the accurate function of the website and the timeliness of the information and links; and
- (4) Include prominent language on the website explaining that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages and written translation available in each non-

English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

- (b) CMS must report on its website the results of the reporting requirements specified at § 441.311 that the State reports to CMS.
- (c) These requirements are effective 3 years after the date of enactment of this paragraph; and in the case of the State that implements a managed care delivery system under the authority of sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Act and includes HCBS in the MCO's, PIHP's, or PAHP's contract, the first managed care plan contract rating period that begins on or after 3 years after the date of enactment of this paragraph.
- 13. Amend § 441.450 in paragraph (c) by adding, in alphabetical order, the definition of "Service plan" to read as follows:

§ 441.450 Basis, scope, and definitions.

* * * * * * (c) * *

Service plan means the written document that specifies the services and supports (regardless of funding source) that are to be furnished to meet the needs of a participant in the self-directed PAS option and to assist the participant to direct the PAS and to live in the community. The service plan is developed based on the assessment of need using a personcentered and directed process. The service plan supports the participant's engagement in community life and respects the participant's preferences, choices, and abilities. The participant's representative, if any, families, friends, and professionals, as desired or required by the participant, will be involved in the service-planning process. Service plans must meet the requirements of §441.301(c)(3).

- * * * * *
 - 14. Amend § 441.464 by-
 - a. Revising paragraph (d)(2)(v);

b. Redesignating current paragraphs (e) and (f) as paragraphs (g) and (h); and c. Adding a new paragraphs (e) and (f). The revisions and additions read as follows: § 441.464 State assurances. (d) * * *(v) Grievance process, as defined in § 441.301(c)(7) when self-directed PAS include services under a section 1915(c) waiver program. (e) Incident management system. The State operates and maintains an incident management system that identifies, reports, triages, investigates, resolves, tracks, and trends critical incidents and adheres to requirements of § 441.302(a)(6). (f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan, in accordance with § 441.302(k). 15. Amend § 441.474 by adding paragraph (c) to read as follows: § 441.474 Quality assurance and improvement plan. (c) The quality assurance and improvement plan must comply with all components of §§ 441.311 and 441.312 and related reporting requirements relevant to the State's self-directed PAS program. 16. Section 441.486 is added to subpart J to read as follows: § 441.486 Website transparency.

For States subject to the requirements of subpart J, the State must operate a website consistent with § 441.313.

17. Amend § 441.540 by revising paragraph (c) to read as follows:

§ 441.540 Person-centered service plan.

* * * * *

(c) Reviewing the person-centered service plan. The State must ensure that the person-centered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of § 441.301(c)(3).

* * * * *

18. Amend § 441.555 by revising paragraph (b)(2)(iv) to read as follows:

§ 441.555 Support system.

* * * * *

(b) * * *

(2) * * *

(iv) Grievance process, as defined in § 441.301(c)(7).

* * * * *

19. Amend § 441.570 by adding paragraphs (e) and (f) to read as follows:

§ 441.570 State assurances.

- (e) An incident management system in accordance with § 441.302(a)(6) is implemented.
- (f) Payment rates are adequate to ensure a sufficient direct care workforce to meet the needs of beneficiaries and provide access to services in the amount, duration, and scope specified in the person-centered service plan, in accordance with § 441.302(k).

(i) to read as follows: § 441.580 Data collection. (i) Data and information as required in § 441.311. 21. Amend § 441.585 by adding paragraph (d) to read as follows: § 441.585 Quality assurance system. (d) The State must implement the Home and Community-Based Services Quality Measure Set in accordance with § 441.312. 22. Section 441.595 is added to subpart K to read as follows-§ 441.595 Website transparency. For States subject to the requirements of subpart K, the State must operate a website consistent with § 441.313. 23. Amend § 441.725 by revising paragraph (c) to read as follows: § 441.725 Person-centered service plan. (c) Reviewing the person-centered service plan. The State must ensure that the personcentered service plan is reviewed, and revised, as appropriate, based upon the reassessment of functional need as required in § 441.720, at least every 12 months, when the individual's circumstances or needs change significantly, and at the request of the individual. States must adhere to the requirements of $\S 441.301(c)(3)$.

24. Amend § 441.745 by-

a. Redesignating paragraph (a)(1)(iii) as paragraph (a)(1)(iv);

20. Amend § 441.580 by redesignating paragraph (i) as (j), and adding a new paragraph

	d. Ade	d. Adding paragraph (b)(1)(v).							
	The revision and additions read as follows:								
§ 441.745 State plan HCBS administration: State responsibilities and quality improvement.									
	*	*	*	*	*				
	(a) *	*	*						
	(1) *	*	*						
	(iii) Gi	rievance	es. A St	ate mus	st provide individuals with the opportunity to file a grievance				
as defined in section § 441.301(c)(7).									
	*	*	*	*	*				
	(v) A S	State mi	ıst impl	ement a	an incident management system in accordance with				
§441.302(a)(6).									
	(vi) A	State m	ust assu	ıre payı	ment rates are adequate to ensure a sufficient direct care				
workf	orce to 1	neet the	e needs	of bene	ficiaries and provide access to services in the amount,				
duratio	on, and	scope sp	pecified	in the 1	person-centered service plan, in accordance with §				
441.30)2(k).								
	(vii) A State must assure the submission of data and information as required in § 441.311.								
	*	*	*	*	*				
	(b) *	*	*						
	(1) *	*	*						
	(i) Inco	orporate	e a conti	nuous o	quality improvement process that includes monitoring,				
remed	iation, a	ınd qual	ity imp	roveme	nt, including recognizing and reporting critical incidents, as				
defined in § 441.302(a)(6)(i)(A).									
	*	*	*	*	*				

b. Adding new paragraphs (a)(iii) and (a)(v) through (vii);

c. Revising paragraph (b)(1)(i); and

(v) Implementation of the Home and Community-Based Services Quality Measure Set in accordance with § 441.312.

* * * * *

25. Section § 441.750 is added to subpart M to read as follows-

§ 441.750 Website transparency.

For States subject to the requirements of subpart M, the State must operate a website consistent with § 441.313.

* * * * *

PART 447 PAYMENT FOR SERVICES

26. The authority citation for part 447 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1396r-8, and Pub. L. 111–148.

27. Amend § 447.203 by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 447.203 Documentation of access to care and service payment rates.

* * * * *

(b)(1) Payment rate transparency. The State agency is required to publish all Medicaid fee-for-service payment rates on a website developed and maintained by the single State agency that is accessible to the general public. Published Medicaid fee-for-service payment rates include fee schedule payment rates made to providers delivering Medicaid services to Medicaid beneficiaries through a fee-for-service delivery system. The website where the State agency publishes its Medicaid fee-for-service payment rates must be easily reached from a hyperlink on the State Medicaid agency's website. Medicaid fee-for-service payment rates must be organized in such a way that a member of the public can readily determine the amount that Medicaid would pay for the service and, in the case of a bundled or similar payment methodology, identify each constituent service included within the rate and how much of the bundled payment is allocated to each constituent service under the State's methodology. If the rates vary, the State must

separately identify the Medicaid fee-for-service payment rates by population (pediatric and adult), provider type, and geographical location, as applicable. The initial publication of the Medicaid fee-for-service payment rates shall occur no later than January 1, 2026 and include approved Medicaid fee-for-service payment rates in effect as of January 1, 2026. The agency is required to include the date the payment rates were last updated on the State Medicaid agency's website and to ensure these data are kept current where any necessary update must be made no later than 1 month following the date of CMS approval of the State plan amendment, section 1915(c) HCBS waiver amendment, or similar amendment revising the provider payment rate or methodology. In the event of a payment rate change that occurs in accordance with a previously approved rate methodology, the State will update its payment rate transparency publication no later than 1 month after the effective date of the most recent update to the payment rate.

- (2) Comparative payment rate analysis and payment rate disclosure. The State agency is required to develop and publish a comparative payment rate analysis of Medicaid payment rates for each of the following categories of services in paragraphs (b)(2)(i) through (iii) of this section and a payment rate disclosure of Medicaid payment rates for each of the following categories of services in paragraph (b)(2)(iv) of this section, as specified in paragraph (b)(3) of this section. If the rates vary, the State must separately identify the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.
 - (i) Primary care services.
 - (ii) Obstetrical and gynecological services.
 - (iii) Outpatient behavioral health services.
- (iv) Personal care, home health aide, and homemaker services, as specified in § 440.180(b)(2) through (4), provided by individual providers and providers employed by an agency.
- (3) Comparative payment rate analysis and payment rate disclosure requirements. The State agency must develop and publish, consistent with the publication requirements described in

paragraph (b)(1) of this section for payment rate transparency data, a comparative payment rate analysis and a payment rate disclosure.

- (i) For the categories of services described in paragraph (b)(2)(i) through (iii) of this section, the comparative payment rate analysis must compare the State agency's Medicaid feefor-service payment rates to the most recently published Medicare payment rates effective for the same time period for the evaluation and management (E/M) codes applicable to the category of service. The State must conduct the comparative payment rate analysis at the Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) code level, as applicable, using the most current set of codes published by CMS, and the analysis must meet the following requirements:
- (A) The State must organize the analysis by category of service as described in paragraphs (b)(2)(i) through (iii) of this section.
- (B) The analysis must clearly identify the Medicaid base payment rates for each E/M CPT/HCPCS code identified by CMS under the applicable category of service, including, if the rates vary, separate identification of the payment rates by population (pediatric and adult), provider type, and geographical location, as applicable.
- (C) The analysis must clearly identify the Medicare non-facility payment rates effective for the same time period for the same set of E/M CPT/HCPCS codes, and for the same geographical location as the Medicaid base payment rates, that correspond to the Medicaid base payment rates identified under paragraph (b)(3)(i)(B) of this section, including, separate identification of the payment rates by provider type.
- (D) The analysis must specify the Medicaid base payment rate identified under paragraph (b)(3)(i)(B) of this section as a percentage of the Medicare non-facility payment rate identified under paragraph (b)(3)(i)(C) of this section for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.

- (E) The analysis must specify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the Medicaid base payment rate is published pursuant to paragraph (b)(3)(i)(B) of this section.
- (ii) For each category of services specified in paragraph (b)(2)(iv) of this section, the State agency is required to publish a payment rate disclosure that expresses the State's payment rates as the average hourly payment rates, separately identified for payments made to individual providers and to providers employed by an agency, if the rates vary. The payment rate disclosure must meet the following requirements:
 - (A) The State must organize the payment rate disclosure by category of service as specified in paragraph (b)(2)(iv) of this section.
- (B) The disclosure must identify the average hourly payment rates by applicable category of service, including, if the rates vary, separate identification of the average hourly payment rates for payments made to individual providers and to providers employed by an agency, by population (pediatric and adult), provider type, and geographical location, as applicable.
- (C) The disclosure must identify the number of Medicaid-paid claims and the number of Medicaid enrolled beneficiaries who received a service within a calendar year for each of the services for which the average hourly payment rates are published pursuant to paragraph (b)(3)(ii)(B) of this section.
- (4) Comparative payment rate analysis and payment rate disclosure timeframe. The State agency must publish the initial comparative payment rate analysis and payment rate disclosure of its Medicaid payment rates in effect as of January 1, 2025 as required under paragraphs (b)(2) and (b)(3) of this section, by no later than January 1, 2026. Thereafter, the State agency must update the comparative payment rate analysis and payment rate disclosure no less than every 2 years, by no later than January 1 of the second year following the most recent update. The comparative payment rate analysis and payment rate disclosure must be published consistent

with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data.

- (5) Compliance with payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements. If a State fails to comply with the payment rate transparency, comparative payment rate analysis, and payment rate disclosure requirements in paragraphs (b)(1) through (b)(4) of this section, including requirements for the time and manner of publication, future grant awards may be reduced under the procedures set forth at 42 CFR part 430, subparts C and D by the amount of FFP CMS estimates is attributable to the State's administrative expenditures relative to the total expenditures for the categories of services specified in paragraph (b)(2) of this section for which the State has failed to comply with applicable requirements, until such time as the State complies with the requirements. Unless otherwise prohibited by law, deferred FFP for those expenditures will be released after the State has fully complied with all applicable requirements.
- (6) Interested parties advisory group for rates paid for certain services. (i) The State agency must establish an advisory group for interested parties to advise and consult on provider rates with respect to service categories under the Medicaid State plan, 1915(c) waiver, and demonstration programs, as applicable, where payments are made to the direct care workers specified in § 441.302(k)(1)(ii) for the self-directed or agency-directed services found at § 440.180(b)(2) through (4).
- (ii) The interested parties advisory group must include, at a minimum, direct care workers, beneficiaries, beneficiaries' authorized representatives, and other interested parties impacted by the services rates in question, as determined by the State.
- (iii) The interested parties advisory group will advise and consult with the Medicaid agency on current and proposed payment rates, HCBS payment adequacy data as required at § 441.311(e), and access to care metrics described in § 441.311(d)(2), associated with services found at § 440.180(b)(2) through (4), to ensure the relevant Medicaid payment rates are

sufficient to ensure access to personal care, home health aide, and homemaker services for Medicaid beneficiaries at least as great as available to the general population in the geographic area and to ensure an adequate number of qualified direct care workers to provide self-directed personal assistance services.

- (iv) The interested parties advisory group shall meet at least every 2 years and make recommendations to the Medicaid agency on the sufficiency of State plan, 1915(c) waiver, and demonstration direct care worker payment rates, as applicable. The State agency will ensure the group has access to current and proposed payment rates, HCBS provider payment adequacy minimum performance and reporting standards as described in § 441.311(e), and applicable access to care metrics as described in § 441.311(d)(2) for HCBS in order to produce these recommendations. The process by which the State selects interested party advisory group members and convenes its meetings must be made publicly available.
- (v) The Medicaid agency must publish the recommendations produced under paragraph (b)(6)(iv) of the interested parties advisory group consistent with the publication requirements described in paragraph (b)(1) of this section for payment rate transparency data, within 1 month of when the group provides the recommendation to the agency.
- (c)(1) Initial State analysis for rate reduction or restructuring. For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the criteria in paragraphs (c)(1)(i) through (iii) of this section are met, the State agency must provide written assurance and relevant supporting documentation that the following conditions are met as well as a description of the State's procedures for monitoring continued compliance with section 1902(a)(30)(A) of the Act, as part of the State plan amendment submission in a format prescribed by CMS as a condition of approval:
- (i) Medicaid payment rates in the aggregate (including base and supplemental payments) following the proposed reduction or restructuring for each benefit category affected by the

proposed reduction or restructuring would be at or above 80 percent of the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services.

- (ii) The proposed reduction or restructuring, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year, would be likely to result in no more than a 4 percent reduction in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.
- (iii) The public processes described in paragraph (c)(4) of this section and § 447.204 of this part yielded no significant access to care concerns from beneficiaries, providers, or other interested parties regarding the service(s) for which the payment rate reduction or payment restructuring is proposed, or if such processes did yield concerns, the State can reasonably respond to or mitigate the concerns, as appropriate, as documented in the analysis provided by the State pursuant to § 447.204(b)(3).
- (2) Additional State rate analysis. For any State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access where the requirements in paragraphs (c)(1)(i) through (iii) of this section are not met, the State must also provide the following to CMS as part of the State plan amendment submission as a condition of approval, in addition to the information required under paragraph (c)(1) of this section, in a format prescribed by CMS:
- (i) A summary of the proposed payment change, including the State's reason for the proposal and a description of any policy purpose for the proposed change, including the cumulative effect of all reductions or restructurings taken throughout the current State fiscal year in aggregate fee-for-service Medicaid expenditures for each benefit category affected by proposed reduction or restructuring within a State fiscal year.

- (ii) Medicaid payment rates in the aggregate (including base and supplemental payments) before and after the proposed reduction or restructuring for each benefit category affected by proposed reduction or restructuring, and a comparison of each (aggregate Medicaid payment before and after the reduction or restructuring) to the most recently published Medicare payment rates for the same or a comparable set of Medicare-covered services and, as reasonably feasible, to the most recently available payment rates of other health care payers in the State or the geographic area for the same or a comparable set of covered services.
- (iii) Information about the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring. For this purpose, an actively participating provider is a provider that is participating in the Medicaid program and actively seeing and providing services to Medicaid beneficiaries or accepting Medicaid beneficiaries as new patients. The State must provide the number of actively participating providers of services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of actively participating providers in each geographic area over this period. The State may provide estimates of the anticipated effect on the number of actively participating providers of services in each benefit category affected by the proposed reduction or restructuring, by geographic area.
- (iv) Information about the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number of beneficiaries receiving services in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish). The State must document observed trends in the number of Medicaid beneficiaries receiving services in each affected benefit category in each geographic area over this period.

The State must provide quantitative and qualitative information about the beneficiary populations receiving services in the affected benefit categories over this period, including the number and proportion of beneficiaries who are adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery for beneficiaries in various populations. The State must provide estimates of the anticipated effect on the number of Medicaid beneficiaries receiving services through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.

- (v) Information about the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring. The State must provide the number Medicaid services furnished in each affected benefit category for each of the 3 years immediately preceding the State plan amendment submission date, by State-specified geographic area (for example, by county or parish), provider type, and site of service. The State must document observed trends in the number of Medicaid services furnished in each affected benefit category in each geographic area over this period. The State must provide quantitative and qualitative information about the Medicaid services furnished in the affected benefit categories over this period, including the number and proportion of Medicaid services furnished to adults and children and who are living with disabilities, and a description of the State's consideration of the how the proposed payment changes may affect access to care and service delivery. The State must provide estimates of the anticipated effect on the number of Medicaid services furnished through the FFS delivery system in each benefit category affected by the proposed reduction or restructuring, by geographic area.
- (vi) A summary of, and the State's response to, any access to care concerns or complaints received from beneficiaries, providers, and other interested parties regarding the service(s) for which the payment rate reduction or restructuring is proposed as required under § 447.204(a)(2).

- (3) Compliance with requirements for State analysis for rate reduction or restructuring. A State that submits a State plan amendment that proposes to reduce provider payment rates or restructure provider payments in circumstances when the changes could result in diminished access that fails to provide the information and analysis to support approval as specified in paragraphs (c)(1) and (2) of this section, as applicable, may be subject to State plan amendment disapproval under § 430.15(c) of this chapter. Additionally, States that submit relevant information, but where there are unresolved access to care concerns related to the proposed State plan amendment, including any raised by CMS in its review of the proposal and any raised through the public process as specified in paragraph (c)(4) of this section or under § 447.204(a)(2), may be subject to State plan amendment disapproval. If State monitoring of beneficiary access after the payment rate reduction or restructuring takes effect shows a decrease in Medicaid access to care, such as a decrease in the provider-to-beneficiary ratio for any affected service, or the State or CMS experiences an increase in beneficiary or provider complaints or concerns about access to care that suggests possible noncompliance with the access requirements in section 1902(a)(30)(A) of the Act, CMS may take a compliance action using the procedures described in § 430.35 of this chapter.
- (4) Mechanisms for ongoing beneficiary and provider input. (i) States must have ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or another equivalent mechanisms), consistent with the access requirements and public process described in § 447.204.
- (ii) States should promptly respond to public input through these mechanisms citing specific access problems, with an appropriate investigation, analysis, and response.
- (iii) States must maintain a record of data on public input and how the State responded to this input. This record will be made available to CMS upon request.
- (5) Addressing access questions and remediation of inadequate access to care. When access deficiencies are identified, the State must, within 90 days after discovery, submit a

corrective action plan with specific steps and timelines to address those issues. While the corrective action plan may include longer-term objectives, remediation of the access deficiency should take place within 12 months.

- (i) The State's corrective actions may address the access deficiencies through a variety of approaches, including, but not limited to: Increasing payment rates, improving outreach to providers, reducing barriers to provider enrollment, providing additional transportation to services, providing for telemedicine delivery and telehealth, or improving care coordination.
 - (ii) The resulting improvements in access must be measured and sustainable.
- (6) Compliance actions for access deficiencies. To remedy an access deficiency, CMS may take a compliance action using the procedures described at § 430.35 of this chapter.
 - 28. Amend § 447.204 by—
 - a. Revising paragraphs (a)(1) and (b); and
 - b. Removing paragraph (d).

The revisions read as follows:

§ 447.204 Medicaid provider participation and public process to inform access to care.

- (a) * * *
- (1) The data collected, and the State analysis performed, under § 447.203(c).
- * * * * *
- (b) The State must submit to CMS with any such proposed State plan amendment affecting payment rates documentation of the information and analysis required under § 447.203(c) of this chapter.

* * * * *

Dated:	April	24,	2023

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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